AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

Federal Register

7–19–01 Thursday
Vol. 66 No. 139 July 19, 2001
Pages 37575–37880

The **FEDERAL REGISTER** 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.

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 http://www.nara.gov/fedreg.

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** 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 it includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward.

GPO Access users can choose to retrieve online **Federal Register** documents as TEXT (ASCII text, graphics omitted), PDF (Adobe Portable Document Format, including full text and all graphics), or SUMMARY (abbreviated text) files. Users should carefully check retrieved material to ensure that documents were properly downloaded.

On the World Wide Web, connect to the **Federal Register** at http://www.access.gpo.gov/nara. Those without World Wide Web access can also connect with a local WAIS client, by Telnet to swais.access.gpo.gov, or by dialing (202) 512-1661 with a computer and modem. When using Telnet or modem, type swais, then log in as guest with no password.

For more information about GPO Access, contact the GPO Access User Support Team by E-mail at gpoaccess@gpo.gov; by fax at (202) 512–1262; or call (202) 512–1530 or 1–888–293–6498 (toll free) between 7 a.m. and 5 p.m. Eastern time, Monday–Friday, except Federal holidays.

The annual subscription price for the **Federal Register** paper edition is $638, or $697 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 $253. Six month subscriptions are available for one-half the annual rate. The charge for individual copies in paper form is $9.00 for each issue, or $9.00 for each group of pages as actually bound; or $2.00 for each issue in microfiche form. All prices include regular domestic postage and handling. International customers please add 25% for foreign handling. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard or Discover. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.

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: 66 FR 12345.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

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

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

Single copies/back copies:

Paper or fiche	**512–1800**
Assistance with public single copies	**512–1803**

FEDERAL AGENCIES

Subscriptions:

Paper or fiche	**523–5243**
Assistance with Federal agency subscriptions	**523–5243**

Printed on recycled paper.

Contents

Federal Register

Vol. 66, No. 139

Thursday, July 19, 2001

Agriculture Department
See Animal and Plant Health Inspection Service
See Farm Service Agency
See Rural Business-Cooperative Service
See Rural Housing Service
See Rural Utilities Service

Air Force Department
NOTICES
Meetings:
Interface Control Working Group; L2 and L5 signal structures, 37655

Alcohol, Tobacco and Firearms Bureau
RULES
Alcoholic beverages:
Additional ameliorating material use in certain wines, 37576–37578
PROPOSED RULES
Alcoholic beverages:
American wines; new prime grape variety names, 37609–37611

Animal and Plant Health Inspection Service
RULES
Plant-related quarantine, domestic:
Karnal bunt, 37575–37576

Antitrust Division
NOTICES
National cooperative research notifications:
Financial Services Technology Consortium, Inc., 37708
J Consortium, Inc., 37708
Management Services Providers Association, Inc., 37708–37709
Microcontaminant Reduction Venture, 37709
National Center for Manufacturing Sciences, Inc., 37709

Army Department
See Engineers Corps
NOTICES
Military traffic management:
Capacity loads; modifications, 37655–37656
Patent licenses; non-exclusive, exclusive, or partially exclusive:
Anthrax vaccines, 37656
Differentially acting OP detoxifying sponges, 37657
Immobilized enzymes as biosensors for chemical toxins, 37657
Monoclonal antibodies to cholesterol and methods, 37657
OP detoxifying sponges composed of multiple immobilized enzymes of cholinesterases and OP hydrolases and oximes as reactivators, rapid method to make, 37657–37658
Organophosphates, compositions for use to deactivate, 37658

Centers for Disease Control and Prevention
NOTICES
Grants and cooperative agreements; availability, etc.:
Human immunodeficiency virus (HIV)—
HIV-positive persons; prevention intervention research studies, 37694–37696

Coast Guard
RULES
Drawbridge operations:
Florida, 37578–37580
Ports and waterways safety:
Captain of the Port of Detroit Zone, MI; safety zones, 37580–37581
Genesee River, Rochester, NY; safety zone, 37584–37585
Niagara River, NY; safety zone, 37585–37587
Oswego Harbor, NY; safety zone, 37581–37582
Presque Isle Bay, PA; safety zone, 37582–37583
PROPOSED RULES
Drawbridge operations:
Florida, 37615–37616

Commerce Department
See Foreign-Trade Zones Board
See International Trade Administration
See National Oceanic and Atmospheric Administration

Comptroller of the Currency
PROPOSED RULES
Community Reinvestment Act regulations; review, 37602–37608

Defense Department
See Air Force Department
See Army Department
See Defense Logistics Agency
See Engineers Corps
NOTICES
Arms sales notification; transmittal letter, etc., 37643–37654
Meetings:
Scientific Advisory Board, 37654–37655

Defense Logistics Agency
NOTICES
Privacy Act:
Computer matching programs, 37658–37659

Education Department
NOTICES
Grants and cooperative agreements; availability, etc.:
Elementary and secondary education and vocational and adult education—
Smaller Learning Communities Program, 37871–37876
Special education and rehabilitative services:
Blind vending facilities under Randolph-Sheppard Act—
Arbitration panel decisions, 37660–37661

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Meetings:
Environmental Management Site-Specific Advisory Board—
Oak Ridge Reservation, TN, 37661–37662
Rocky Flats, CO, 37662

Engineers Corps
NOTICES
Environmental statements; notice of intent:
Lee and Bastrop Counties, TX; Three Oaks Surface Lignite Mine; construction and operation, 37660

Environmental Protection Agency
RULES
Air pollutants, hazardous; national emission standards:
Kraft, soda, sulfite, and stand-alone semichemical pulp mills; chemical recovery combustion sources; technical corrections, 37591–37593
Air programs:
Stratospheric ozone protection—
Methyl bromide; quarantine and preshipment applications; exemptions, 37751–37769
Air quality implementation plans; approval and promulgation; various States:
California, 37587–37591
Pesticide programs:
Plant-incorporated protectants (formerly plant-pesticides),
Nucleic acids residues; tolerance requirement exemption, 37816–37830
Sexually compatible plants; residues derived through conventional breeding; tolerance requirement exemption, 37829–37854
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Avermectin, etc., 37593–37599
PROPOSED RULES
Pesticide programs:
Plant-incorporated protectants (formerly plant-pesticides)—
Plants sexually compatible with recipient plant; exemptions, 37854–37869
Water supply:
National primary drinking water regulations—
Arsenic; compliance and new source contaminants monitoring; clarifications, 37617–37631
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 37671–37672
Air pollution control:
Citizens suits; proposed settlements—
Clean Air Implementation Project et al., 37672–37673
Meetings:
Intel XL Project extension; stakeholders, 37673
Pesticide, food, and feed additive petitions:
Syngenta Crop Protection, Inc., 37677–37681
Pesticide registration, cancellation, etc.:
Diazinon, 37673–37677

Farm Credit Administration
NOTICES
Meetings:
Other financing institutions and alternative funding mechanisms, 37681

Farm Service Agency
NOTICES
Agency information collection activities:
Proposed collection; comment request, 37637

Federal Communications Commission
RULES
Radio stations; table of assignments:
Texas, 37599
PROPOSED RULES
Common carrier services:
Individuals with hearing and speech disabilities; telecommunications relay services, 37631–37632
Radio stations; table of assignments:
Texas, 37632–37633
NOTICES
Agency information collection activities:
Proposed collection; comment request, 37681–37682
Reporting and recordkeeping requirements, 37682–37684
Common carrier services:
Wireless telecommunications services—
Enhanced 911 Phase II Automatic Location Identification requirements; waiver petitions; comment request, 37684–37685

Federal Deposit Insurance Corporation
PROPOSED RULES
Community Reinvestment Act regulations; review, 37602–37608

Federal Election Commission
NOTICES
Meetings; Sunshine Act, 37685

Federal Energy Regulatory Commission
NOTICES
Electric rate and corporate regulation filings:
Bonneville Power Adminstration et al., 37664–37667
Environmental statements; availability, etc.:
Florida Gas Transmission Co., 37667
Municipal Dam Hydro Project, 37667–37668
Hydroelectric applications, 37668–37671
Practice and procedure:
Off-the-record communications, 37671
Applications, hearings, determinations, etc.:
Calhoun Power Co. I, LLC, 37662–37663
Natural Gas Pipeline Co. of America, 37663
New York Independent System Operator, Inc., 37663
Tuscarora Gas Transmission Co., 37663–37664

Federal Maritime Commission
NOTICES
Ocean transportation intermediary licenses:
A.R. Savage & Son, Inc., et al., 37685
A.W. Fenton Co., Inc., et al., 37685–37686

Federal Railroad Administration
NOTICES
Environmental statements; notice of intent:
Maglev deployment program—
Baltimore, MD and Washington, DC, 37721
Pittsburgh et al., PA, 37721–37722

Federal Reserve System
PROPOSED RULES
Community Reinvestment Act regulations; review, 37602–37608
NOTICES
Banks and bank holding companies:
Change in bank control, 37686
Formations, acquisitions, and mergers, 37686
Organization, functions, and authority delegations, 37686–37690

Federal Retirement Thrift Investment Board
NOTICES
Meetings; Sunshine Act, 37690

Financial Management Service
See Fiscal Service

Fiscal Service
NOTICES
Surety companies acceptable on Federal bonds:
Highlands Insurance Co. et al.; termination, 37723

Foreign-Trade Zones Board
NOTICES
Applications, hearings, determinations, etc.:
Missouri, 37638

General Services Administration
RULES
Federal Management Regulation:
Federal advisory committee management; revision, 37727–37750

Health and Human Services Department
See Centers for Disease Control and Prevention
See National Institutes of Health
NOTICES
Grants and cooperative agreements; availability, etc.:
HIV/AIDS Regional Resource Network Program, 37690–37694
Meetings:
Genetic Testing Advisory Committee, 37694

Housing and Urban Development Department
NOTICES
Grant and cooperative agreement awards:
Research and technology unsolicited proposals, 37699–37700
Rural Housing and Economic Development Program, 37700–37702
Grants and cooperative agreements; availability, etc.:
Urban empowerment zones; Round III designation, 37877–37882

Interior Department
See Minerals Management Service
See Reclamation Bureau

Internal Revenue Service
NOTICES
Agency information collection activities:
Proposed collection; comment request, 37723–37724

International Trade Administration
NOTICES
Antidumping:
Cased pencils from—
China, 37638–37639
Porcelain-on-steel cookware from—
Mexico, 37640
Preserved mushrooms from—
Chile, 37640
Various countries, 37640–37641
Welded carbon steel pipe and tube from—
Turkey, 37641

International Trade Commission
NOTICES
Import investigations:
Garage door operators, including components, 37704–37705
Oscillating sprinklers, sprinkler components, and nozzles, 37705
Semiconductor light emitting devices, components, and products containing same, 37705–37706

Justice Department
See Antitrust Division
NOTICES
Pollution control; consent judgments:
Clark Refining & Marketing, Inc., 37706
National Railroad Passenger Corp., 37706–37707
Rockford, IL, 37707
Wisconsin et al., 37707–37708

Libraries and Information Science, National Commission
See National Commission on Libraries and Information Science

Minerals Management Service
PROPOSED RULES
Outer Continental Shelf; oil, gas, and sulphur operations:
Offshore cranes; American Petroleum Institute's Specification 2C; incorporation by reference, 37611–37615

National Aeronautics and Space Administration
NOTICES
Meetings:
Advisory Council
Minority Business Resource Advisory Committee, 37710
U.S. Centennial of Flight Commission, 37710

National Commission on Libraries and Information Science
NOTICES
Meetings; Sunshine Act, 37709–37710

National Council on Disability
NOTICES
Meetings:
International Watch Advisory Committee, 37710–37711

National Highway Traffic Safety Administration
NOTICES
Motor vehicle safety standards:
Nonconforming vehicles—
Importation eligibility; determinations, 37722–37723

National Institutes of Health
NOTICES
Meetings:
National Cancer Institute, 37697
National Institute of Child Health and Human Development, 37697–37698
National Library of Medicine, 37698–37699

National Oceanic and Atmospheric Administration
RULES
Fishery conservation and management:
Alaska; fisheries of Exclusive Economic Zone—
Sablefish, 37600–37601
Shortraker and rougheye rockfish, 37600
Marine mammals:
Steller sea lions; Bogoslof Island, AK; no-entry zone exemption, 37599–37600
PROPOSED RULES
Fishery conservation and management:
Caribbean, Gulf, and South Atlantic fisheries—
Gulf of Mexico shrimp, 37634–37635

Caribbean, Gulf, and South Atlantic fisheries, and Gulf of Mexico and South Atlantic spiny lobster—
Tortugas Marine Reserves establishment, 37635–37636
Magnuson-Stevens Act provisions—
Domestic fisheries; exempted fishing permits, 37634
NOTICES
Environmental statements; availability, etc.:
Gray whales; International Whaling Commission quota issuance to Makah Tribe (2001 and 2002), 37641–37642
Permits:
Marine mammals, 37642

Public Debt Bureau
See Fiscal Service

Public Health Service
See Centers for Disease Control and Prevention
See National Institutes of Health

Reclamation Bureau
NOTICES
Environmental statements; availability, etc.:
Glenn, Colusa, and Yolo Counties, CA; Colusa Basin flood control program, 37702–37703
Environmental statements; notice of intent:
Central Valley Project, CA; Sacramento River settlement contracts renewal, 37703–37704

Rural Business-Cooperative Service
NOTICES
Agency information collection activities:
Proposed collection; comment request, 37637

Rural Housing Service
NOTICES
Agency information collection activities:
Proposed collection; comment request, 37637

Rural Utilities Service
NOTICES
Agency information collection activities:
Proposed collection; comment request, 37637

Securities and Exchange Commission
NOTICES
Investment Company Act of 1940:
Exemption applications—
Morgan Grenfell Investment Trust et al., 37711–37712
Joint industry plan:
National Association of Securities Dealers, Inc., et al., 37712–37714
Self-regulatory organizations:
Clearing agency registration applications—
Government Securities Clearing Corp., 37714–37715
Self-regulatory organizations; proposed rule changes:
New York Stock Exchange, Inc., 37715–37716
Pacific Exchange, Inc., 37716–37720

Thrift Supervision Office
PROPOSED RULES
Community Reinvestment Act regulations; review, 37602–37608

Transportation Department
See Coast Guard
See Federal Railroad Administration
See National Highway Traffic Safety Administration
NOTICES
Aviation proceedings:
Agreements filed, etc., 37720
Certificates of public convenience and necessity and foreign air carrier permits; weekly applications, 37720–37721

Treasury Department
See Alcohol, Tobacco and Firearms Bureau
See Comptroller of the Currency
See Fiscal Service
See Internal Revenue Service
See Thrift Supervision Office

Veterans Affairs Department
NOTICES
Agency information collection activities:
Proposed collection; comment request, 37724–37725
Submission for OMB review; comment request, 37725–37726
Meetings:
Rehabilitation Research and Development Service Scientific Merit Review Board, 37726

Separate Parts In This Issue

Part II
General Services Administration, 37727–37750

Part III
Environmental Protection Agency, 37751–37769

Part IV
Environmental Protection Agency, 37771–37869

Part V
Department of Education, 37871–37876

Part VI
Department of Housing and Urban Development, 37877–37882

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.

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.

7 CFR
301.....37575

12 CFR
Proposed Rules:
25.....37602
228.....37602
345.....37602
563e.....37602

27 CFR
4.....37576
24.....37576
Proposed Rules:
4.....37609

30 CFR
Proposed Rules:
250.....37611

33 CFR
117 (2 documents) 37578, 37579
165 (5 documents) 37580, 37581, 37582, 37584, 37585
Proposed Rules:
117.....37615

40 CFR
52.....37587
63.....37591
82.....37752
152.....37772
174 (3 documents) 37772, 37817, 37830
180.....37593
Proposed Rules:
141.....37617
142.....37617
174.....37855

41 CFR
101-6.....37728
102-3.....37728

47 CFR
73.....37599
Proposed Rules:
64.....37631
73 (3 documents) 37632, 37633

50 CFR
223.....37599
679 (2 documents) 37600
Proposed Rules:
600.....37634
622 (2 documents) 37634, 37635
640.....37635

Rules and Regulations

Federal Register
Vol. 66, No. 139
Thursday, July 19, 2001

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

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 01–063–1]

Karnal Bunt; Regulated Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the Karnal bunt regulations by adding Archer and Baylor Counties in Texas to the list of regulated areas. This action is precipitated by the detection of bunted kernels in samples taken from bins of wheat grain stored in Baylor County and harvested in Archer and Baylor Counties. This action will help prevent the spread of Karnal bunt into noninfected areas of the United States.

DATES: This interim rule was effective July 13, 2001. We invite you to comment on this docket. We will consider all comments that we receive by September 17, 2001.

ADDRESSES: Please send four copies of your comment (an original and three copies) to: Docket No. 01–063–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Please state that your comment refers to Docket No. 01–063–1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Spaide, Director for Surveillance and Emergency Programs Planning and Coordination, PPQ, APHIS, 4700 River Road, Unit 98, Riverdale, MD 20737–1231; (301) 734–7819.

SUPPLEMENTARY INFORMATION:

Background

Karnal bunt is a fungal disease of wheat (*Triticum aestivum*), durum wheat (*Triticum durum*), and triticale (*Triticum aestivum* X *Secale cereale*), a hybrid of wheat and rye. Karnal bunt is caused by the fungus *Tilletia indica* (Mitra) Mundkur and is spread by spores, primarily through the planting of infected seed. Some countries in the international wheat market regulate Karnal bunt as a fungal disease requiring quarantine; therefore, without measures taken by the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture, to prevent its spread, the presence of Karnal bunt in the United States could have significant consequences with regard to the export of wheat to international markets. The regulations regarding Karnal bunt are set forth in 7 CFR 301.89–1 through 301.89–16 (referred to below as the regulations).

Regulated Areas

The regulations in § 301.89–3(e) provide that we will classify a field or area as a regulated area when it is:

- A field planted with seed from a lot found to contain a bunted wheat kernel;
- A distinct definable area that contains at least one field that was found during a survey to contain a bunted wheat kernel. The distinct definable area may include an area where Karnal bunt is not known to exist but where intensive surveys are required because of the areas's proximity to a field found during survey to contain a bunted kernel; or
- A distinct definable area that contains at least one field that was found during survey to contain spores consistent with Karnal bunt and has been determined to be associated with grain at a handling facility containing a bunted wheat kernel. The distinct definable area may include an area where Karnal bunt is not known to exist but where intensive surveys are required because of that area's proximity to a field that has been associated with grain at a handling facility containing a bunted kernel.

The boundaries of distinct definable areas are determined using the criteria in paragraphs (b) through (d) of § 301.89–3, which provide for the regulation of less than an entire State, the inclusion of noninfected acreage in a regulated area, and the temporary designation of nonregulated areas as regulated areas. Paragraph (c) of § 301.89–3 states that the Administrator may include noninfected acreage within a regulated area due to its proximity to an infestation or inseparability from the infected locality for regulatory purposes, as determined by:

- Projections of the spread of Karnal bunt along the periphery of the infestation;
- The availability of natural habitats and host materials within the noninfected acreage that are suitable for establishment and survival of Karnal bunt; and
- The necessity of including noninfected acreage within the regulated area in order to establish readily identifiable boundaries.

The regulations at § 301.89–3(f) set the boundaries for regulated areas in Arizona, California, New Mexico, and Texas. Certain regulated areas in Arizona, California, and Texas include noninfected acreage that functions as a buffer zone to guard against the spread of Karnal bunt.

When we include noninfected acreage in a regulated area for one or more of the reasons previously listed, the noninfected acreage, along with the rest of the acreage in the regulated area, is intensively surveyed. Negative results from surveys of the noninfected acreage provide assurance that all infected acreage is within the regulated area. In effect, the noninfected acreage serves as a buffer zone between fields or areas associated with a bunted kernel and areas outside of the regulated area.

In this document, we are adding Archer and Baylor Counties, in their entirety, to the list of regulated areas in

Texas. This action is necessary due to the detection of bunted wheat kernels in samples taken from bins of wheat grain stored in Baylor County. The wheat grain was harvested in Archer and Baylor Counties. Until APHIS completes its detection and delimiting surveys, the entirety of each county will be designated as a regulated area in order to include all fields that have a reasonable possibility of being infected.

Emergency Action

This rulemaking is necessary on an emergency basis to prevent Karnal bunt from spreading to noninfected areas of the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 533 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we are amending 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 166, 7711, 7712, 7714, 7731, 7735, 7751, 7752, 7753, and 7754; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 also issued under Sec. 204, Title II, Pub. L. 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 also issued under Sec. 203, Title II, Pub. L. 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

2. In § 301.89–3, paragraph (f), under the heading for ''Texas'', add two new entries in alphabetical order to read as follows:

§ 301.89–3 Regulated areas.

* * * * *

(f) * * *

Texas

Archer County. The entire county.

Baylor County. The entire county.

* * * * *

Done in Washington, DC. this 13th day of July 2001.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01–18071 Filed 7–18–01; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 4 and 24

RIN: 1512–AB78

[T.D. ATF–458]

Implementation of Public Law 105–34, Section 1417, Related to the Use of Additional Ameliorating Material in Certain Wines (98R–89P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Treasury Decision, final rule.

SUMMARY: This final rule implements one of the provisions of the Taxpayer Relief Act of 1997. In accordance with the law, ATF is amending the regulations to extend the amelioration and sweetening limitations so that wines made exclusively from any fruit (excluding grapes) or berry with a fixed acid content of 20 or more parts per thousand are entitled to a volume of up to 60 percent ameliorating material. To provide agreement with the IRC, the regulations are changed to raise the maximum limit on alcohol content derived from fermentation from 13 percent to 14 percent in ameliorated fruit (excluding grape) and citrus wines.

EFFECTIVE DATE: These regulations are retroactive to April 1, 1998.

FOR FURTHER INFORMATION CONTACT: Jennifer Berry, Bureau of Alcohol, Tobacco and Firearms, Regulations Division, 111 W. Huron Street, Room 219, Buffalo, New York 14202–2301, (716) 551–4048.

SUPPLEMENTARY INFORMATION:

Background

This final rule implements one of the provisions of the Taxpayer Relief Act of 1997, Public Law 105–34 (''the Act''). Section 1417 of the Act amended section 5384(b)(2)(D) of the Internal Revenue Code of 1986 by striking ''loganberries, currants, or gooseberries,'' and inserting ''any fruit or berry with a natural fixed acid of 20 parts per thousand or more (before any correction to such fruit or berry).'' Section 5384 relates to wines other than grape wines.

Previous Regulation for Amelioration of Fruit and Berries

Before enactment of the Act, the amelioration and sweetening limitations of 26 U.S.C. 5384 (b)(2)(D) could only be used for wines produced exclusively from loganberries, currants, or

gooseberries. For wine produced exclusively from loganberries, currants, or gooseberries, the volume of ameliorating material added to juice or wine may not have exceeded 60 percent of the total volume of ameliorated juice or wine (calculated exclusive of pulp). If the starting fixed acid level was or exceeded 12.5 grams per liter, a maximum of 1,500 gallons of ameliorating material may have been added to each 1,000 gallons of wine or juice.

Section 1417 of Public Law 105–34 now extends the amelioration and sweetening limitations so that wines made from any fruit or berry with a natural fixed acid of 20 parts per thousand or more (before any correction of such fruit or berry) is entitled to a volume of up to 60 percent ameliorating material. These provisions do not apply to grape wine, only to fruit or berry wine.

T.D. ATF–403 and Notice No. 868

On September 13, 1999, ATF issued a temporary rule, T. D. ATF–403 (64 FR 50252), to implement section 1417 of Public Law 105–34. In accordance with the law, the regulations were amended to extend the amelioration and sweetening limitations so that a wine made from any fruit or berry with a natural fixed acid of 20 parts per thousand or more (before any correction of such fruit or berry) is entitled to a volume of up to 60 percent ameliorating material. These provisions do not apply to grape wine, only to fruit or berry wine. On the same day, ATF also issued Notice No. 868 (64 FR 50265) inviting comments on the temporary rule.

Comment Received in Response to Notice No. 868

ATF received one letter of comment, from E. & J. Gallo Winery (Gallo), in response to Notice No. 868. Gallo's comments addressed four separate issues raised by the rulemaking, issues discussed in detail below.

• Gallo noted that in the temporary regulations at 27 CFR 4.21(e), ATF deleted the reference to the maximum ameliorating limit of 35% for other fruit (those having a normal acidity of less than 20 parts or more per thousand). Gallo pointed out that Public Law 105–34 did not change this limit and its deletion from the regulation could cause confusion. Upon reviewing this section of the regulations, we concur that the deletion of this reference to the 35 percent limit is unnecessary and could be confusing. Accordingly, the phrase ''and in the case of other fruit wines, not more than 35 percent'' will be added back to § 4.21(e).

• In its second point, Gallo commented that § 4.21(d), the standard of identity for citrus wines, should be amended to reflect the new amelioration and sweetening limits granted by Public Law 105–34. The law amended section 5384(b)(2)(D) of the IRC by striking ''loganberries, currants, or gooseberries,'' and inserting ''any fruit or berry with a natural fixed acid of 20 parts per thousand or more (before any correction to such fruit or berry).'' We note that § 4.21(d) states that citrus wines may be ameliorated and sweetened in accordance with section 5384 of the IRC. Also, while section 5383 of the IRC contains separate amelioration and sweetening provisions for grape wines, the IRC does not contain separate provisions for citrus wines. We therefore agree with Gallo that the new amelioration and sweetening limits apply to citrus wines. Accordingly, § 4.21(d) is being amended so that citrus wines with a fixed acid content of 20 parts or more per thousand are entitled to a volume of up to 60 percent ameliorating material.

• In its review of Notice 868, Gallo also noted an inconsistency between the regulation of amelioration in 26 U.S.C. 5384(a) and part 4. 26 U.S.C. 5384(a), states ''To natural wine made from berries or fruit other than grapes, pure dry sugar or liquid sugar may be added to the juice in the fermenter, or to the wine after fermentation; but only if such wine has not more than 14 percent alcohol by volume after complete fermentation, or after complete fermentation and sweetening * * *'' Gallo contrasted this with § 4.21(d)(1)(i) and (e)(1)(i), the standards of identity for citrus and fruit wines respectively, which both state ''* * * but in no event shall any product so ameliorated have an alcoholic content, derived by fermentation, of more than 13% alcohol by volume * * *''.

A review of the legislative history of section 5384 revealed that its current limitation of 14 percent is the result of Public Law 90–619 of 1968. Prior to this amendment, section 5384 read as follows: ''* * * but only if such wine has less than 14 percent alcohol by volume after complete fermentation, or after complete fermentation and sweetening * * *''. In contrast, the limitation of 13 percent in § 4.21 was in place prior to 1968 and was not changed to agree with the amendments implemented by Public Law 90–619.

ATF agrees that part 4 should be corrected to be consistent with section 5384 of the IRC. We are therefore amending § 4.21(d)(1)(i) and (e)(1)(i) by raising the maximum limit on alcohol content derived from fermentation from 13 percent to 14 percent in ameliorated wines.

• In its final point, Gallo commented that the temporary regulations at § 24.178(b)(4) contain an apparent error. The words ''or wine'' were omitted in the following sentence, with the omission shown in italics: ''For wine produced from any fruit (excluding grapes) or berry with a natural fixed acid of 20 parts per thousand or more (before any correction of such fruit or berry), the volume of ameliorating material added to juice or wine may not exceed 60 percent of the total volume of ameliorated juice or wine (calculated exclusive of pulp).'' As this omission was indeed a typographical error, the words ''or wine'' will be added back to § 24.178(b)(4).

Regulatory Flexibility Act

It is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities. The rule merely conforms the regulations to changes in the law made by the Taxpayer Relief Act of 1997. Also, this regulation will not impose any recordkeeping or reporting requirements. Accordingly, a regulatory flexibility analysis is not required.

Executive Order 12866

It has been determined that this regulation is not a significant regulatory action as defined by Executive Order 12866. Accordingly, this final rule is not subject to the analysis required by this Executive Order.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because no requirement to collect information is imposed.

Administrative Procedure Act

The effective date limitation in 5 U.S.C. 553(d) does not apply to this Treasury Decision as it merely implements a section of the law which was effective April 1, 1998, and it does not differ substantively from the temporary rule (T.D. ATF–403) published September 13, 1999.

Drafting Information

The principal author of this document is Jennifer Berry, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 4

Advertising, Customs duties and inspection, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Trade Practices, Wine.

27 CFR Part 24

Administrative practice and procedure, Claims, Electronic fund transfers, Excise taxes, Exports, Food additives, Fruit juices, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Research, Scientific equipment, Spices and flavoring, Surety bonds, Vinegar, Warehouses, Wine.

Authority and Issuance

Accordingly, Chapter I of title 27, Code of Federal Regulations is amended as follows:

PART 4—LABELING AND ADVERTISING OF WINE

Paragraph 1. The authority citation for 27 CFR part 4 continues to read as follows:

Authority: 27 U.S.C. 205, unless otherwise noted.

Par. 2. Section 4.21 is amended by revising the provisos in paragraphs (d)(1)(i) and (e)(1)(i) to read as follows:

§ 4.21 The standards of identity.

* * * * *

(d) Class 4; citrus wine.

(1)(i) * * * *Provided,* That a domestic product may be ameliorated or sweetened in accordance with the provisions of 26 U.S.C. 5384 and any product other than domestic may be ameliorated before, during, or after fermentation by adding, separately or in combination, dry sugar, or such an amount of sugar and water solution as will not increase the volume of the resulting product more than 35 percent, or in the case of products produced from citrus fruit having a normal acidity of 20 parts or more per thousand, not more than 60 percent, but in no event shall any product so ameliorated have an alcoholic content, derived by fermentation, of more than 14 percent by volume, or a natural acid content, if water has been added, of less than 5 parts per thousand, or a total solids content or more than 22 grams per 100 cubic centimeters.

* * * * *

(e) *Class 5:* fruit wine.

(1)(i) * * * *Provided,* That a domestic product may be ameliorated or sweetened in accordance with the provisions of 26 U.S.C. 5384 and any product other than domestic may be ameliorated before, during, or after fermentation by adding, separately or in combination, dry sugar, or such an amount of dry sugar and water solution as will increase the volume of the resulting product, in the case of wines produced from any fruit or berry other than grapes, having a normal acidity of 20 parts or more per thousand, not more than 60 percent, and in the case of other fruit wines, not more than 35%, but in no event shall any product so ameliorated have an alcoholic content, derived by fermentation, of more than 14 percent by volume, or a natural acid content, if water has been added, of less than 5 parts per thousand, or a total solids content of more than 22 grams per 100 cubic centimeters.

* * * * *

Par. 3. Section 4.22 is amended by revising the proviso in paragraph (b)(5) to read as follows:

§ 4.22 Blends, cellar treatment, alteration of class or type.

* * * * *

(b) * * *

(5) * * * *Provided,* That the class or type thereof shall not be deemed to be altered where such wine (other than grape wine) is derived from fruit, or other agricultural products, having a high normal acidity, if the total solids content is not more than 22 grams per 100 cubic centimeters, and the content of natural acid is not less than 7.5 parts per thousand and where such wine is derived exclusively from fruit, or other agricultural products, the normal acidity of which is 20 parts or more per thousand, if the volume of the resulting product has been increased not more than 60 percent by the addition of sugar and water solution, for the sole purpose of correcting natural deficiencies due to such acidity, and (except in the case of such wine when produced from fruit or berries other than grapes) there is stated as part of the class and type designation the phrase ''Made with over 35 percent sugar solution.''

PART 24—WINE

Paragraph 1. The authority citation for 27 CFR Part 24 continues to read as follows:

Authority: 5 U.S.C. 552(a); 26 U.S.C. 5001, 5008, 5041, 5042, 5044, 5061, 5062, 5081, 5111–5113, 5121, 5122, 5142, 5143, 5173, 5206, 5214, 5215, 5351, 5353, 5354, 5356, 5357, 5361, 5362, 5364–5373, 5381–5388, 5391, 5392, 5511, 5551, 5552, 5661, 5662, 5684, 6065, 6091, 6109, 6301, 6302, 6311, 6651, 6676, 7011, 7302, 7342, 7502, 7503, 7606, 7805, 7851; 31 U.S.C. 9301, 9303, 9304, 9306.

Par. 2. Section 24.178 is amended by revising paragraphs (b)(3) and (b)(4) to read as follows:

§ 24.178 Amelioration.

* * * * *

(b) * * *

(3) For all wine, except for wine described in paragraph (b)(4) of this section, the volume of ameliorating material added to juice or wine may not exceed 35 percent of the total volume of ameliorated juice or wine (calculated exclusive of pulp). Where the starting fixed acid level is or exceeds 7.69 grams per liter, a maximum of 538.4 gallons of ameliorating material may be added to each 1,000 gallons of wine or juice.

(4) For wine produced from any fruit (excluding grapes) or berry with a natural fixed acid of 20 parts per thousand or more (before any correction of such fruit or berry), the volume of ameliorating material added to juice or wine may not exceed 60 percent of the total volume of ameliorated juice or wine (calculated exclusive of pulp). If the starting fixed acid level is or exceeds 12.5 grams per liter, a maximum of 1,500 gallons of ameliorating material may be added to each 1,000 gallons of wine or juice. (26 U.S.C. 5383, 5384).

* * * * *

Signed: June 14, 2001.

Bradley A. Buckles,

Director.

Approved: June 28, 2001.

Timothy E. Skud,

Acting Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 01–17936 Filed 7–18–01; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD07–01–073]

Drawbridge Operation Regulations; State Road 84 Bridge, South Fork of the New River, Mile 4.4, Fort Lauderdale, Broward County, FL

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the State Road 84 bridge across the South Fork of the New River, Fort Lauderdale, Florida. This deviation allows the drawbridge owner or

operator to not open the bridge for a period of time. This temporary deviation is required to allow the bridge owner to safely complete repairs of the bridge.

DATES: This deviation is effective from August 2, 2001 to August 20, 2001.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Chief, Operations Section, Seventh Coast Guard District, Bridge Section at (305) 415–6743.

SUPPLEMENTARY INFORMATION: The State Road 84 bridge across the South Fork of the New River at Fort Lauderdale, Broward County, Florida is a single leaf bridge with a vertical clearance of 21 feet above mean high water (MHW) measured at the fenders in the closed position with a horizontal clearance of 40 feet. On June 20, 2001, the Florida Department of Transportation, the drawbridge owner, requested a deviation from the current operating regulation in 33 CFR 117.315(b) which requires the draw of the State Road 84 bridge, mile 4.4 at Fort Lauderdale, to open on signal if at least 24 hours notice is given. This temporary deviation will allow the bridge owner to complete necessary repairs to the drawbridge in a critical time sensitive manner.

The District Commander has granted a temporary deviation from the operating requirements listed in 33 CFR 117.315(b) for the purpose of repair completion of the drawbridge. Under this deviation, the State Road 84 bridge need not open from August 2, 2001 through August 9, 2001. Additionally, from August 10 to August 20, 2001, the bridge need not open except in the event of heavy weather with an opening schedule broadcast locally during this period.

Dated: July 9, 2001.

Greg E. Shapley,

Chief, Bridge Administration, Seventh Coast Guard District.

[FR Doc. 01–17997 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD07–01–053]

RIN 2115–AE47

Drawbridge Operation Regulations: Miami River, Miami, Dade County, FL

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is permanently changing the operating regulations of all drawbridges on the Miami River, from the mouth to and including the N.W. 27th Avenue bridge, mile 3.7, Miami, FL. This rule will allow the bridge owner or operator to open the bridge on signal for all Federal holidays, in addition to the six listed in the current regulation.

DATES: This rule is effective August 20, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket [CGD07–01–053] and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 S.E. 1st Avenue, Miami, FL 33131, between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Project Officer, Seventh Coast Guard District, Bridge Branch, at (305) 415–6743.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On January 10, 2001, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations: Miami River, Miami, Dade County, FL in the **Federal Register**. (66 FR 1923). We did not receive any letters commenting on the proposed rule. No public hearing was requested and none was held.

Background and Purpose

The current rule governing the Miami River Drawbridges, from the mouth to and including the N.W. 27th Avenue bridge, mile 3.7, is inconsistent with current bridge operating practices on Federal holidays. The current regulation was written when there were only six Federal holidays. That regulation states that the bridge can open on signal during those six holidays listed in the regulation. This rule will change the bridge operating regulations to include all Federal holidays and will reduce confusion of which Federal holidays apply.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT)(44 FR 11040, February 26, l979). This rule only changes the bridge operating schedule to include all Federal holidays instead of only some Federal holidays.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this final rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this final rule would not have a significant economic impact on a substantial number of small entities because the rule only slightly alters the current bridge operating schedule.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding this rule.

We also have a point of contact for commenting on actions by employees of the Coast Guard. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This final rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that this rule does not have implications for federalism.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Environment

We considered the environmental impact of this rule and concluded that, under, Figure 2–1, paragraph 32(e) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket where indicated under **ADDRESSES.**

Indian Tribal Governments

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

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Section 117.305 is revised to read as follows:

§ 117.305 Miami River.

The draw of each bridge from the mouth to and including N.W. 27th Avenue bridge, mile 3.7 at Miami, shall open on signal; except that, from 7:30 a.m. to 9 a.m. and 4:30 p.m. to 6 p.m. Monday through Friday except Federal holidays, the draws need not be opened for the passage of vessels. Public vessels of the United States and vessels in an emergency involving danger to life or property shall be passed at any time.

Dated: July 2, 2001.

James S. Carmichael,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 01–17996 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09–01–090]

Safety Zone: Captain of the Port Detroit Zone

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: The Coast Guard is implementing safety zones for annual fireworks displays in the Captain of the Port Detroit Zone during August 2001. This action is necessary to provide for the safety of life and property on navigable waters during these events. These zones will restrict vessel traffic from a portion of the Captain of the Port Detroit Zone.

DATES: 33 CFR 165.907 (a)(22) and (a)(23) will be implemented from 9 p.m. through 11:59 p.m. (EST) on August 11, 2001.

FOR FURTHER INFORMATION CONTACT: Ensign Brandon Sullivan, U.S. Coast Guard Marine Safety Office Detroit, (313) 568–9580.

SUPPLEMENTARY INFORMATION: The Coast Guard is implementing two permanent safety zones in 33 CFR 165.907 (published May 21, 2001, in the **Federal Register,** 66 FR 27868), for fireworks displays in the Captain of the Port Detroit Zone during August 2001. The following safety zones are in effect for fireworks displays occurring in the month of August 2001:

(1) *Maritime Day Fireworks, Marine City, MI.* Location: All waters of the St. Clair River within a 300-yard radius of the fireworks barge in approximate position 42°43′ N, 082°29′ W, about 500 yards east of Marine City, St. Clair River on August 11, 2001 from 9 p.m. to 11:59 p.m.

(2) *Venetian Festival Boat Parade & Fireworks, St. Clair Shores, MI.* Location: All waters of Lake St. Clair within a 300-yard radius of the fireworks barge in approximate position 42°28′N, 082°52′ W, about 600 yards off Jefferson Beach Marina, Lake St. Clair on August 11, 2001 from 9 p.m. to 11:59 p.m. In order to ensure the safety of spectators and transiting vessels, this safety zone will be in effect for the duration of the event. Vessels may not enter the safety zone without permission from Captain of the Port Detroit Zone. If you would like permission, contact the person listed in **FOR FURTHER INFORMATION CONTACT.** Spectator vessels may anchor outside the safety zone but are cautioned not to block a navigable channel.

Dated: July 10, 2001.

B.P. Hall,

Lieutenant Commander, U.S. Coast Guard, Acting Captain of the Port Detroit.

[FR Doc. 01–17998 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09–01–083]

RIN 2115–AA97

Safety Zone; Oswego Harbor, Oswego, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone encompassing the navigable waters of Oswego Harbor. The safety zone is necessary to ensure the safety of spectators and vessels from the hazards associated with fireworks displays. This safety zone is intended to restrict vessel traffic from a portion of Lake Ontario and Oswego Harbor, New York.

DATES: This rule is effective from 9:30 p.m. until 10 p.m. on July 28, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD09–01–083 and are available for inspection or copying at U.S. Coast Guard Marine Safety Office Buffalo, 1 Fuhrmann Blvd, Buffalo, New York 14203 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant David Flaherty, U. S. Coast Guard Marine Safety Office Buffalo, 1 Fuhrmann Blvd, Buffalo, New York 14203. The telephone number is (716) 843–9574.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM, and, under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard had insufficient advance notice to publish an NPRM followed by a temporary final rule that would be effective before the necessary date. Publication of a notice of proposed rulemaking and delay of effective date would be contrary to the public interest because immediate action is necessary to prevent possible loss of life, injury, or damage to property. The Coast Guard has not received any complaints or negative comments with regard to this event.

Background and Purpose

A temporary safety zone is necessary to ensure safety of vessels, spectators, and participants for the Oswego Harborfest fireworks display. The safety zone consists of all navigable waters of Oswego Harbor within an 800 foot radius around the fireworks barge located at 43°28′0″ N, 076°31′9″ W. All geographic coordinates are North American Datum of 1983 (NAD 83). Entry into, transit through or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative. The designated on-scene representative will be the Patrol Commander and may be contacted via VHF/FM Marine Channel 16.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979).

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Marine Safety Office Buffalo (see **ADDRESSES.**)

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

The Coast Guard considered the environmental impact of this regulation and concluded that, under figure 2–1, paragraph (34)(g) of Commandant Instruction M16475.1C, it is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subject in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. A new temporary § 165.T09–970 is added to read as follows:

§ 165.T09–970 Safety Zone; Oswego Harbor, Oswego, NY.

(a) *Location.* The following area is a temporary safety zone: all waters of Oswego Harbor within an 800-foot radius around the fireworks barge located at 43°28′0″ N, 076°31′9″ W. All geographic coordinates are North American Datum of 1983 (NAD83).

(b) *Effective time and date.* This rule is effective from 9:30 p.m. until 10 p.m. (local) on July 28, 2001. The designated Patrol Commander on scene may be contacted on VHF–FM Channel 16.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Coast Guard Captain of the Port, Buffalo, or the designated Patrol Commander.

Dated: July 5, 2001.

S.D. Hardy,

Commander, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 01–18109 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09–01–084]

RIN 2115–AA97

Safety Zone; Presque Isle Bay, Erie, Pennsylvania

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone encompassing the navigable waters in Presque Isle Bay. The safety zone is necessary to ensure the safety of spectators and vessels from the hazards associated with fireworks displays. This safety zone is intended to restrict vessel traffic from a portion of Presque Isle Bay, Erie, Pennsylvania.

DATES: This rule is effective from 9:30 p.m. through 10:30 p.m. on August 19, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD09–01–084 and are available for inspection or copying at U.S. Coast Guard Marine Safety Office Buffalo, 1 Fuhrmann Blvd, Buffalo, New York 14203 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant David Flaherty, U. S. Coast Guard Marine Safety Office Buffalo, 1 Fuhrmann Blvd, Buffalo, New York 14203. The telephone number is (716) 843–9574.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM, and, under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard had insufficient advance notice to publish an NPRM followed by a temporary final rule that would be effective before the necessary date. Publication of a notice of proposed rulemaking and delay of effective date would be contrary to the public interest because immediate action is necessary to prevent possible loss of life, injury, or damage to property. The Coast Guard has not received any complaints or negative comments with regard to this event

Background and Purpose

A temporary safety zone is necessary to ensure safety of vessels, spectators, and participants for the We Love Erie Days fireworks display. Entry into, transit through or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative. The designated on-scene representative will be the Patrol Commander and may be contacted via VHF/FM Marine Channel 16.

The safety zone will encompass all navigable waters of Presque Isle Bay within an 800-foot arc of the fireworks launch platform located at the end of Dobbins Landing in position 42°08′19″ N, 080°05′30″ W. These coordinates are based upon North American Datum 1983 (NAD 83).

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of

the Department of Transportation (DOT) (44 FR 11040, February 26, 1979).

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Marine Safety Office Buffalo (see **ADDRESSES**.)

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

The Coast Guard considered the environmental impact of this regulation and concluded that, under figure 2–1, paragraph (34)(g) of Commandant Instruction M16475.1C, it is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subject in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. A new temporary § 165.T09–969 is added to read as follows:

§ 165.T09–969 Safety Zone; Presque Isle Bay, Erie, PA.

(a) *Location:* The following area is a temporary safety zone: all navigable waters of Presque Isle Bay within an 800-foot arc around the fireworks launch platform located at the end of Dobbins Landing in approximate position 42°08′19″ N, 080°05′30″ W (NAD 83).

(b) *Effective time and date.* This section is effective from 9:30 p.m. until 10:30 p.m. (local) on August 19, 2001.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Coast Guard Captain of the Port, Buffalo, or the designated Patrol Commander.

Dated: July 5, 2001.

S. D. Hardy,

Commander, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 01–18108 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09–01–014]

RIN 2115–AA97

Safety Zone; Rochester Harborfest Fireworks Display, Genesee River, Rochester, New York

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone, encompassing the navigable waters of Rochester Harbor and the Genesee River in Rochester, New York. This rule is necessary to protect participants, vessels, and spectators from the hazards associated with the storage, preparation, and launching of fireworks. The rule is intended to restrict vessel traffic from a portion of the waters of Rochester Harbor and the Genesee River, Rochester, New York.

DATES: This rule is effective from 9 p.m. until 11 p.m. (EST) on August 11, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD09–01–014 and are available for inspection or copying at U.S. Coast Guard Marine Safety Office Buffalo, 1 Fuhrmann Blvd., Buffalo, NY 14203 between 8 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant David Flaherty, U.S. Coast Guard Marine Safety Office Buffalo, 1 Fuhrmann Blvd., Buffalo, NY 14203. The phone number is (716) 843–9574.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds good cause exists for not publishing an NPRM, and, under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard had insufficient advance notice to publish an NPRM followed by a temporary final rule. Publication of an NPRM and delay of the effective date would be contrary to the public interest because immediate action is necessary to prevent possible loss of life, injury, or damage to property.

Background and Purpose

This safety zone is being established to ensure the safety of vessels, spectators and participants. All persons and vessels shall comply with the instructions of the Captain of the Port Buffalo or the designated on scene patrol personnel. Entry into, transit through or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or the designated Patrol Commander. The designated Patrol Commander may be contacted via VHF/FM Marine Channel 16.

Regulatory Evaluation

This temporary rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulation Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not review it under that order. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of the DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule will have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities: the owners or operators of vessels intending to transit or anchor in a portion of Rochester Harbor from 9 p.m. to 11 p.m. (EST) on August 11, 2001.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. This rule will be in effect for only two hours late in the day when vessel traffic is low. Vessel traffic may enter or transit through the safety zone with the permission of Captain of the Port Buffalo or the designated Patrol Commander. Before the effective period, we will issue maritime advisories, widely available to users of the harbor.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Marine Safety Office Buffalo (See **ADDRESSES**).

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132, Federalism, and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Environment

We have considered the environmental impact of this rule and concluded that under figure 2–1, paragraph (34)(g) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES**.

Indian Tribal Governments

This temporary final rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. A rule with tribal implications has a substantial direct effect on one or more Indian tribe, 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.

Energy Effects

We have analyzed this proposed rule under Executive order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a statement of Energy Effects under Executive Order 13211.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A new temporary § 165.T09–945 is added to read as follows:

§ 165.T09–945 Safety Zone; Rochester Harborfest Fireworks Display, Genesee River, Rochester, New York.

(a) *Location.* The following area is a temporary safety zone: all waters of Rochester Harbor and the Genesee River encompassed by an area 300-yards around the fireworks barge moored/anchored in approximate position: 43°15.8′ N 077°36.0′ W. These coordinates are based on North American Datum 1983 (NAD 83).

(b) *Effective time and date.* This section is effective from 9 p.m. through 11 p.m. (EST) on August 11, 2001.

(c) *Regulations.*

(1) The general regulations contained in 33 CFR 165.23 apply.

(2) All persons and vessels shall comply with the instructions of the Captain of the Port Buffalo or the designated on scene patrol personnel. Entry into, transit through or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or the designated Patrol Commander. Coast Guard patrol personnel include commissioned, warrant or petty officers of the U.S. Coast Guard. Upon being hailed by a U.S. Coast Guard vessel via siren, radio, flashing light, or other means, the operator shall proceed as directed. The Captain of the Port Buffalo or the designated Patrol Commander may be contacted via VHF Channel 16.

Dated: June 21, 2001.

S.D. Hardy,

Commander, U.S. Coast Guard Captain of the Port Buffalo.

[FR Doc. 01–18107 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09–01–010]

RIN 2115–AA97

Safety Zone; Niagara River, Tonawanda, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone. The safety zone encompasses the navigable waters on the Niagara River in Tonawanda, New York. The action is necessary to protect participants and non-participants within the immediate area from the hazards associated with fireworks displays.

DATES: This rule is effective from 9:30 p.m. until 10:30 p.m. on July 22, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD09–01–010] and are available for inspection of copying at U.S. Coast Guard Marine Safety Office Buffalo, 1 Fuhrmann Blvd, Buffalo, NY 14203, between 8 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant David Flaherty, U. S. Coast Guard Marine Safety Office Buffalo, 1 Fuhrmann Blvd, Buffalo, NY. The telephone number is (716) 843–9574.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM, and, under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard had insufficient advance notice to publish an NPRM followed by a temporary final rule that would be effective before the necessary date. Publication of a notice of proposed rulemaking and delay of effective date would be contrary to the public interest because immediate action is necessary to prevent possible loss of life, injury, or damage to property. The Coast Guard has not received any complaints or negative comments with regard to this event.

Background and Purpose

A temporary safety zone is required to ensure safety of vessels and participants. Entry into, transit through or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port, Buffalo or the designated Patrol Commander. The designated Patrol Commander on scene may be contacted on Marine VHF Channel 16.

Regulatory Evaluation

This temporary rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) the Coast Guard considered whether this rule will have a significant impact on a substantial number of small businesses and not-for-profit organizations that are not dominant in their respective fields, and government jurisdictions with populations less than 50,000. For the same reasons set forth in the above regulatory evaluations, the Coast Guard certifies under section 605 (b) of the Regulatory Flexibility Act (5 U.S.C.601 *et seq.*) that this temporary final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), the Coast Guard wants to assist small entities in understanding this rule so that they can better evaluate its effectiveness and participate in the rulemaking process. If your small business or organization is affected by this rule, and you have questions concerning its provisions or options for compliance, please contact the office listed in **ADDRESSES** in this preamble.

Collection of Information

This rule contains no information collection requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 13132 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This event is being conducted in concurrence with local authorities.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local or tribal government or the private sector to incur direct costs without the Federal Government having first provided the funds to pay those costs. This temporary final rule would not impose an unfunded mandate.

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

The Coast Guard considered the environmental impact of this regulation and concluded that, under figure 2–1, paragraph (34)(g) of Commandant Instruction M16475.1C, it is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. A new temporary § 165.T09–940 is added to read as follows:

§ 165.T09–940 Safety Zone: Niagara River, Tonawanda, NY.

(a) *Location*. The following area is a temporary safety zone: The waters of the Niagara River within 300 yards of a fireworks barge moored/anchored with its center in approximate position 43 01′ 52″ N, 078 53′ 16″ W. All coordinates in this section reference 1983 North American Datum (NAD83).

(b) *Effective time and date*. This regulation is effective from 9:30 p.m. until 10:30 p.m. (local) July 22, 2001.

(c) *Regulations*. In accordance with the general regulations in § 165.23 of this part, entry into this zone is

prohibited unless authorized by the Coast Guard Captain of the Port Buffalo, or the designated Patrol Commander.

Dated: June 21, 2001.

S.D. Hardy,

Commander, U.S. Coast Guard Captain of the Port Buffalo, NY.

[FR Doc. 01–18106 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–15–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 217–0285; FRL–6995–7]

Final Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, San Joaquin Valley Unified Air Pollution District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing limited approval and limited disapproval of revisions to the California State Implementation Plan (SIP) proposed in the **Federal Register** on September 28, 2000. This limited approval and limited disapproval action will incorporate Rules 2020 and 2201 of San Joaquin Valley Unified Air Pollution District (District) into the federally approved SIP.

The intended effect of finalizing this limited approval is to strengthen the federally approved SIP by incorporating these rules and by satisfying Federal requirements for an approvable nonattainment area New Source Review (NSR) SIP for the District. While strengthening the SIP, however, this SIP revision contains deficiencies which the District must correct before EPA can grant full approval under section 110(k)(3). Thus, EPA is finalizing simultaneous limited approval and limited disapproval as a revision to the California SIP under provisions of the Act regarding EPA action on SIP submittals, and general rulemaking authority.

DATES: This action is effective on August 20, 2001.

ADDRESSES: Copies of the state submittal and other supporting information used in developing the final action are available for public inspection (Docket Numbers NSRR 00–13–CA and NSRR 00–16–CA) at EPA's Region IX office during normal business hours. Copies of the District Rules and submittal are also available at the following locations: San Joaquin Valley Unified Air Pollution Control District, 1990 E. Gettysburg Avenue, Fresno, California 93726. California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1001 ''I'' Street, Sacramento, CA 95812.

FOR FURTHER INFORMATION CONTACT: Ed Pike, Permits Office, (AIR–3), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901; by telephone at (415) 744–1211; or by email at Pike.Ed@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' are used we mean EPA.

Table of Contents

I. What Action Is EPA Finalizing?
II. Background
III. Public Comments and EPA Response
IV. EPA Final Action and Required Corrections to District Rules 2020 and 2201
V. Administrative Requirements

I. What Action Is EPA Finalizing?

EPA is finalizing a limited approval and limited disapproval of revisions to the California SIP for District Rules 2020 and 2201. This final action replaces previous New Source Review and Permit Exemption Rules in the following SIPs: Fresno County, a portion of Kern County, [1] Kings County, Madera County, Merced County, San Joaquin County, Stanislaus County, and Tulare County. Please see the Technical Support Document for a complete list of the Rules that will be replaced.

Rule 2020 was adopted by the San Joaquin Valley Unified Air Pollution Control District on September 17, 1998, and submitted to EPA by the California Air Resources Board (CARB) on October 27, 1998. Rule 2201 was adopted by the District on August 20, 1998 and submitted to EPA by CARB on September 29, 1998. This proposed limited approval and limited disapproval does not include sections 5.9 and 6.0 of Rule 2201, which specify requirements for sources that request permit modifications that also meet title V requirements. The title V requirements in Rule 2201 (based on a prior version of Rule 2201) were given interim approval as part of the District's title V operating permits program in EPA's April 24, 1996 rulemaking on that program (see 60 FR 55517 and 61 FR 18083). The District has not submitted any substantive changes to the title V sections of Rule 2201 since that approval.

[1] See the Technical Support Document and 64 FR 51493 for more background information on the District and its jurisdiction.

II. Background

The background of this action is more lengthy than our usual consideration of SIP rules. Initially, on September 23, 1999, EPA proposed to grant full approval of Rules 2201 and 2020 and requested public comment (64 FR 51493). On October 25, 1999, EPA received a comment (as explained in the ''Response to Comments'' section below) from the California Unions for Reliable Energy (''CURE'') contending that full approval of a provision of Rule 2201 would be inconsistent with federal law. After we evaluated the comment, we determined that finalizing full approval of Rule 2201 would be inappropriate, but we also determined that full disapproval would be inappropriate because Rules 2201 and 2020 overall will strengthen the SIP.

EPA, instead, proposed on September 28, 2000, to grant Rules 2201 and 2020 limited approval and limited disapproval (65 FR 58252). In our September 28, 2000, proposal, EPA stated that we would respond to the comments submitted on both proposals (i.e. the proposal to grant full approval in September 1999 and subsequent proposal to grant limited approval and limited disapproval in September 2000) when taking final action. In that proposed limited approval and limited disapproval, EPA concluded that including Rules 2020 and 2201 would generally strengthen the SIP. However, EPA also identified the following deficiencies in District Rules 2020 and 2201 preventing full approval. (See the September 28, 2000, proposal at 65 FR 58252 for an additional description of the necessary corrections to these two rules).

1. The District must remove the agricultural exemption from District Rule 2020.

2. The District must revise Rule 2201 to provide a mandatory and enforceable remedy to cure any annual shortfall and, in the future, prevent shortfalls in the District's New Source Review Offset Equivalency Tracking System.

3. The District must revise Rule 2201 to ensure that all sources meet the Lowest Achievable Emission Rate (LAER) [2] if they are allowed to make a significant increase in their actual emission rate.

[2] Please note that many California Districts use the term ''Best Available Control Technology'' with a definition equivalent to LAER—please see the TSD for additional information on the District's definition of BACT.

III. Public Comments and EPA Response

As noted above, we provided a 30-day public comment period on our September 23, 1999, proposal to grant full approval of Rules 2201 and 2020. EPA received comments from California Utilities for Reliable Energy (''CURE'') and Enron North America Corporation. EPA also provided a 30-day public comment period on its September 28, 2000, proposal to grant limited approval and limited disapproval. EPA received additional comments from CURE, and comments from the Sierra Club. The comments on our most recent proposal and our responses appear below. (EPA has provided responses to earlier comments in a separate Technical Support Document.)

CURE Comment #1

CURE's comment on EPA's September 2000 proposed limited approval and limited disapproval contends that the District's Offset Equivalency Tracking System (which aggregates and tracks Emission Reduction Credits, or ERCs, on an annual basis) is inconsistent with federal law. CURE asserts that federal law requires a demonstration that every ERC is surplus to all other requirements of the SIP before it can be used as a valid offset. The District's annual Offset Equivalency Tracking System will demonstrate that ERCs (which may have been used previously during the year to offset emissions increases) are surplus to other requirements only at the end of each year (on a 3 year rolling average).

EPA Response to Comment Regarding Tracking System

EPA's August 30, 1999, Technical Support Document (TSD) for its proposed full approval of Rules 2201 and 2020 discussed in detail the statutory offset requirements in the Clean Air Act and the reasons the District's Offset Equivalency Tracking System, combined with the requirement for a mandatory and enforceable remedy for any shortfall, complies with the Act. Generally, the Offset Equivalency Tracking System allows the District to demonstrate annually (at the end of each year) that it has required sufficient offsets that meet all federal offset requirements. EPA has also agreed that the District may include the prior two years' data (for a total of three years) to demonstrate equivalency, as long as the demonstration is still conducted annually. During each of the first two years of the tracking system, the District must either provide a demonstration using only the data collected since the beginning of the tracking system, or review all prior permitting actions during the prior year or two to create a three-year rolling average.

EPA's 1999 TSD explains that on a case-by-case basis the District's ERCs do not meet all federal requirements.[3] Primarily, the District does not require an individual ERC to be ''surplus at the time of use.'' See, e.g., *In Re: Operating Permit Formaldehyde Plant Borden Chemical, Inc.,* Petition No. 6–01–1 (Adm'r Dec. 21, 2000) (''*Borden Order*''), at page 18 (''Under Clean Air Act section 173(c)(2), ERCs must be surplus at the time they are used as offsets.''); Memorandum From John Seitz to David Howekamp Re: Response to Request for Guidance on Use of Pre-1990 ERC's and Adjusting for RACT at Time of Use ''*Seitz Memo*''), at p. 2 (''At a minimum, States must ensure a RACT level of reductions on an area basis for all applicable RACT requirements *at time of ERC use* [footnote omitted] (e.g., at the time of NSR permit issuance).'') In contrast, the District evaluates whether ERCs are surplus to other legal requirements at the time a source submits an application to generate an ERC—not when the ERC is used. During the time between the initial application to generate the ERC and application to use an ERC, new legal requirements can become effective. Those new requirements affect whether the ERC, or a portion of the ERC, is surplus.

CURE's comment does not oppose EPA's conclusion that ERCs must be surplus at the time of use. Rather, CURE's comment challenges EPA's conclusion that an annual equivalency demonstration satisfies section 173 of the Clean Air Act. CURE contends that the Act requires the District to demonstrate that an ERC meets all federal requirements before any permit relying on that ERC may be issued.

EPA does not believe that our approval of the District's Offset Equivalency Tracking System allows the District to violate any federal requirement. The District must demonstrate compliance with all federal requirements, but only requires a demonstration of compliance on an aggregate basis at the end of each year (on a 3 year rolling average). Thus, The District must demonstrate that in the aggregate the ERCs it allowed to be used met or exceeded the surplus requirements and all other federal requirements. We have concluded that the Act allows EPA discretion to approve an annual demonstration of equivalency (in the aggregate) with the federal requirements, based in part on the express language in section 173(c)(1)(A), stating:

> by the time the source is to commence operation, sufficient offsetting emissions reductions have been obtained, such that *total allowable emissions from existing sources in the region, from new or modified sources which are not major emitting facilities and from the proposed source will be sufficiently less than total emissions from existing sources* (as determined in accordance with the regulations under this paragraph) prior to the application for such permit to construct or modify so as to represent when considered together with the plan provisions required under section 7502 of this title) reasonable further progress (as defined in section 7501 of this title); (emphasis added)

The Seitz Memo, referenced above, discusses in part the circumstances under which a state could use ERCs generated before 1990. The Seitz Memo concluded that such ERCs could be used if the state could ''show that the magnitude of pre-1990 ERC's (in total tonnage) was included in the growth factor'' and explicitly listed in attainment plan inventories as such. Seitz Memo , at p. 1. When the Seitz Memo further considered whether ERCs were required to be surplus at the time of use, EPA stated that ''States must ensure a RACT level of reductions on an area basis for all applicable RACT requirements *at the time of ERC use* [footnote omitted] (e.g. at the time of NSR permit issuance).'' Seitz Memo at p. 2. EPA's reasoning that we can approve the District's annual aggregate offset equivalency demonstration under the Act is further strengthened by our approval of the RECLAIM Trading Program for implementation of both RACT and NSR in the South Coast Air Quality Management District, based in part on an offset tracking system that operates on an aggregate basis (61 FR 64292).

Further support for EPA's determination that it can allow the District to demonstrate equivalency on an annual basis rather than for each permit lies in the fact that the Clean Air Act generally establishes pollution

[3] As explained in the TSD, the District must include a number of situations in the offset tracking system that will be used to determine equivalency. Rule 2201 differs from federal requirements because it does not ensure that sources provide offsets that are surplus of all regulatory requirements at the time of use, rather than when an application to generate offsets is filed. In addition, Rule 2201 allows some sources to determine offset applicability and quantities based on potential to emit. It also does not require that new major sources offset their full permitted emissions, as they are required to offset only the quantity of emissions that exceed the District offset trigger. Please see EPA's Technical Support Document (TSD) for additional information on the potential offset short-falls in the District regulation that must be included in the offset tracking system, as well as an explanation of situations when sources are expected to provide more valid credits under the District regulations than under federal offset requirements.

limitations on an annual basis for purposes of permit issuance. For example, section 182(c) defines major sources in serious ozone non-attainment areas based on the tons per year of pollutants emitted, and section 182(c)(10) relies on this definition to specify the quantity of ERCs that are required. In addition, although ERCs must be ''enforceable'' at the time of permit issuance, the language of section 173(c)(1) requires that an ERC be ''in effect'' when a major stationary source is ready to commence operations. As a practical matter, there is generally a lengthy time between when a source is permitted and when it commences operations, providing the District with time to conduct the equivalency demonstration.

The District will demonstrate annually that the offsets issued during the year are surplus to emission reductions required under the Clean Air Act and the State Implementation Plan. This demonstration does not change any of the requirements in the Clean Air Act for ERCs to be creditable. It is an accounting exercise allowing the District to demonstrate yearly that sufficient creditable offsets have been provided on an aggregate basis. EPA believes that it is reasonable to interpret section 173, as discussed in the August 26, 1994 memo and Borden Order, to allow approval of an annual equivalency demonstration.

CURE Comment #2

CURE also commented that EPA should clarify that the District's tracking system applies only to ozone precursors.

EPA Response to Comment Regarding Types of Pollutants Covered by Tracking System

EPA disagrees with CURE because we believe that Clean Air Act section 173 allows approval of an aggregate offset tracking system for pollutants other than ozone precursors to demonstrate that ''surplus'' requirements are met. Although the August 26, 1994 memo only specifically considered ozone precursor emissions, the reasoning underlying the memo was not limited to one pollutant. Therefore, EPA believes it is appropriate to extend the reasoning in the August 26, 1994 memo to pollutants contributing to nonattainment with National Ambient Air Quality Standards for particulate matter under 10 microns in diameter, including precursors such as sulfur oxides, provided the facts and science concerning other emissions are sufficiently similar to the science that was considered for ozone precursors.

For instance, we believe that PM_{10} precursors in the San Joaquin Valley are similar to ozone precursors in several ways. These precursors must react with other compounds in the atmosphere before forming PM_{10}, and continue to react over time and distance as they encounter other pollutants in the atmosphere and different meteorological conditions.[4] Therefore, they tend to have a Regional basis, rather than a localized basis, because they are generally dispersed outside of a localized area before reacting to form PM_{10} and can appropriately be included in the aggregate system for demonstrating compliance with EPA offset requirements. In addition, the District rule prohibits any individual source from causing or making worse a violation of an Ambient Air Quality Standard (section 4.14.2). Sources must perform modeling using EPA-approved modeling guidelines (section 4.14.2) to verify that the stationary source will not cause or contribute to an Ambient Air Quality Standard (except for certain non-major sources that are below the public notice thresholds). These air quality and modeling requirements include PM_{10} and PM_{10} precursors (in addition to other pollutants).

In addition, the District has certified to EPA (see December 7, 1999 letter from Seyed Sadredin to Matt Haber) that the directly emitted PM_{10} from stationary sources is only about 0.22% of the inventory of directly-emitted PM_{10}. For this reason, the exact location of an individual stationary source either generating or using offsets of directly-emitted PM_{10} is unlikely to directly create or worsen a localized PM_{10} non-attainment problem in the San Joaquin Valley. (Please note that the District must ensure, via the offset tracking system, that an amount of ''surplus'' PM_{10} and PM_{10} precursor offsets are provided in the District that are at least equal to the amount required under federal NSR requirements.) Instead, stationary sources are more likely to emit precursors that contribute to an area-wide problem and are appropriately regulated in the aggregate for the purposes of the offset tracking system.

Further, the District does not expect to adopt any new stationary source control measures for directly-emitted PM_{10} and believes that existing ERCs are surplus of existing SIP requirements. Therefore, it is extremely unlikely that the District will need to make any special showing in its annual equivalency demonstration that the offsets being used for directly emitted PM_{10} are surplus. In other words, all of the existing and generated offsets that could be used for a new source of directly-emitted PM_{10} should already be surplus to SIP rule requirements. Therefore, EPA believes that demonstrating, via the offset tracking system, that sufficient PM_{10} offsets are obtained on a program-wide basis will not cause or worsen any local air quality violation in the San Joaquin Valley.

CURE Comment #3

CURE commented favorably on (1) EPA's decision not to finalize a full approval of District Rule 2201 and (2) the decision to repropose the action as a limited disapproval based on the District's failure to include in Rule 2201 a specific and mandatory remedy for any shortfall in the annual equivalency system.

EPA Response

EPA agrees with this comment and is finalizing the requirement supported by the commentor.

Sierra Club Comment

The Sierra Club commented that it supports EPA's proposed limited approval and limited disapproval. In particular, the Sierra Club supports the disapproval of the blanket exemption for agricultural sources, and comments that large agricultural facilities must be required to comply with Clean Air Act standards to achieve clean air goals in the San Joaquin Valley.

EPA Response

EPA agrees with this comment and is finalizing the requirement supported by the commentor.

IV. EPA Final Action and Required Corrections to District Rules 2020 and 2201

For the reasons explained above, the comments submitted on our September 28, 2000 proposal have not changed our evaluation of the rules as described in our proposed limited approval and limited disapproval. EPA is, therefore, finalizing its limited approval and limited disapproval of District Rules 2020 and 2201. Our final action is a limited approval and limited disapproval because the Rules contain deficiencies and are not fully consistent with Clean Air Act requirements, EPA regulations and EPA policy. The District must revise Rule 2020 and 2201 to address the following deficiencies, as described in our September 28, 2000 proposal:

[4] For example, see Meng Zhaoyue and John H. Seinfeld, ''Time scales to achieve atmospheric gas-aerosol equilibrium for volatile species'', Atmospheric Environment, Volume 30, Issue 16, August 1996, Pages 2889–2900.

1. The District must remove the agricultural exemption from District Rule 2020.

2. The District must revise Rule 2201 to provide a mandatory and enforceable remedy to cure any annual shortfall and prevent future shortfalls in the District's New Source Review Offset Equivalency Tracking System. This remedy must take effect automatically if the District does not demonstrate equivalency each year. For instance, the District has suggested requiring that major sources and title I modifications meet federal offset requirements, including using credits that are surplus at time of use and using EPA requirements for calculating offset baselines and quantities.

3. The District must revise Rule 2201 to ensure that all sources install LAER if they are allowed to make a significant increase in their actual emission rate. (See 65 FR 58252 for additional information.) For instance, the District could adopt a rule amendment requiring that these sources comply with LAER.

Because these rule deficiencies are inappropriate for inclusion in the SIP, EPA cannot grant full approval of these rules under section 110(k)(3). Also, because the submitted rules are not composed of separable parts which meet all the applicable requirements of the CAA, EPA cannot grant partial approval of the rule under section 110(k)(3). However, EPA is granting final limited approval of the submitted rules under section 110(k)(3) in light of EPA's authority pursuant to section 301(a) to adopt regulations necessary to further air quality by strengthening the SIP. The final approval is limited because EPA's action also contains a simultaneous limited disapproval. In order to strengthen the SIP, EPA is finalizing limited approval and limited disapproval of District rules under sections 110(k)(3) and 301(a) of the CAA. It should be noted that the rules covered by this final rulemaking have been already been adopted by the District. EPA's final limited disapproval action does not prevent the District or EPA from enforcing these rules. Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the State Implementation Plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

The District will have 18 months from the effective date of this final action to correct the deficiencies delineated by EPA in section IV above, to avoid federal sanctions. See section 179(b) of the CAA. The District's failure to correct the deficiencies will also trigger the Federal implementation plan requirements under 110(c).

V. Administrative Requirements

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. This action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this 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.*). Because this rule approves 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). This rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it 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), because it merely approves 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. This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. 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. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) 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'' issued under the executive order. This 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.*).

The Congressional Review Act, 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. 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 17, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping

requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: May 25, 2001.

Laura Yoshii,

Acting Regional Administrator, Region IX.

Part 52, 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 F—California

2. Section 52.220 is amended by adding paragraphs (c)(260)(i)(B) and (c)(266)(i)(B)(*3*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(260) * * *

(i) * * *

(B) San Joaquin Valley Unified Air Pollution Control District.

(*1*) Rule 2020 adopted on September 17, 1998.

* * * * *

(266) * * *

(i) * * *

(B) * * *

(*3*) Rule 2201 adopted on August 20, 1998.

* * * * *

[FR Doc. 01–17705 Filed 7–18–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–6997–8]

RIN 2060–AI34

National Emission Standards for Hazardous Air Pollutants for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical corrections.

SUMMARY: Under the Clean Air Act (CAA), EPA promulgated the national emission standards for hazardous air pollutants (NESHAP) for chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills on January 12, 2001. The promulgated rule requires new and existing major sources to control emissions of hazardous air pollutants (HAP) to the level reflecting application of the maximum achievable control technology. The technical corrections in this action will not change the standards established by the rule or the level of health protection it provides.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. We have determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because the changes to the rule are minor technical corrections consisting largely of correcting typographical errors and other misprints and correcting minor errors in the rule's effective dates, are noncontroversial, and do not substantively change the requirements of the rule. In addition, there has already been full opportunity to comment on all of the provisions in this Notice. Thus, notice and public procedure are unnecessary. We find that this constitutes good cause under 5 U.S.C. 553(b)(B) (see also the final sentence of section 307(d)(1) of the Clean Air Act, 42 U.S.C. section 7607(d)(1), indicating that the good cause provisions of the Administrative Procedure Act continue to apply to this type of rulemaking under the Clean Air Act).

Section 553(d)(3) allows an agency, upon a finding of good cause, to make a rule effective immediately. Because today's changes do not substantively change the requirements of the rule, we find good cause to make these technical corrections effective immediately.

EFFECTIVE DATE: July 19, 2001.

ADDRESSES: Docket No. A–94–67 contains the supporting information for the original NESHAP for chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical mills and this action. The docket is located at the U.S. EPA in room M–1500, Waterside Mall (ground floor), 401 M Street SW., Washington, DC 20460, and may be inspected from 8 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Telander, Minerals and Inorganic Chemicals Group, Emission Standards Division (MD–13), Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5427, facsimile number (919) 541–5600, electronic mail address telander.jeff@epa.gov.

SUPPLEMENTARY INFORMATION:

Regulated Entities. Categories and entities potentially regulated by this action are those kraft, soda, sulfite, and stand-alone semichemical pulp mills with chemical recovery processes that involve the combustion of spent pulping liquor. Categories and entities potentially regulated by this action include:

Category	SIC code	NAICS code	Examples of regulated entities
Industry	2611, 2621, 2631	32211, 32212, 32213 ...	Kraft, soda, sulfite, and stand-alone semichemical pulp mills.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action.

To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in § 63.860 of the final rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this document.

World Wide Web (WWW). In addition to being available in the docket, an electronic copy of today's document will also be available on the WWW

through the Technology Transfer Network (TTN). Following the signature, a copy of this action will be posted on the TTN's policy and guidance page for newly proposed or final rules at http://www.epa.gov/ttn/oarpg/t3pfpr.html. The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541–5384.

I. Background

The EPA, under 40 CFR part 63, subpart MM, promulgated the NESHAP for chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills on January 12, 2001 (66 FR 3180). The final rule includes emissions limits, as well as monitoring, performance testing, recordkeeping, and reporting requirements.

II. Summary of Corrections

Today's changes are described below for the convenience of the reader.

Citation	Change
§ 63.863(a)	Change the compliance date for existing affected sources to March 13, 2004.
§ 63.863(b)	Change the startup date, after which new affected sources must comply immediately upon startup, to March 13, 2001.
§ 63.865(a)	Reduce the number of referenced paragraphs from ''(a)(1) through (4)'' to ''(a)(1) and (2)'' to reflect the elimination of paragraphs (a)(3) and (4).
§ 63.865(a)(3), (a)(4), (b)(5), and (b)(6).	Remove paragraphs (a)(3) and (4) from § 63.865(a) and revise and redesignate them as new paragraphs § 63.865(b)(5) and (6) so that these requirements will no longer be limited under § 63.865(a) to existing sources using the PM bubble compliance alternative.
§ 63.865(b)	Change the reference from ''63.862(a)'' to ''§ 63.862(a) or (b)'' so as to include the new source standards under § 63.862(b). Also, increase the number of referenced paragraphs from ''(b)(1) through (4)'' to ''(b)(1) through (6)'' to reflect the addition of paragraphs (b)(5) and (6).
§ 63.865(b)(2)	Change the reference from ''paragraph (a)(1) or (2) of § 63.862'' to ''paragraph (a) or (b) of § 63.862'' so as to include the new source standards under § 63.862(b).
§ 63.865(b)(4)	Revise Equation 8 so that the numerator and denominator of the oxygen correction factor are reversed to yield: $Q_{corr} = Q_{meas} \times (21 - Y)/(21 \times X)$. Also, reorder the definition of terms for Equation 8 to place ''Y'' before ''X.''
§ 63.865(c)	Add a reference to Methods 1 through 4 to the reference to Method 308 because those four test methods are also needed.
	Because Methods 1 through 4 are also being referenced, clarify that the sampling time and sample volume apply to each Method 308 run.
§ 63.865(d)	Add a reference to Methods 1 through 4 to the reference to Method 25A because those four test methods are also needed. Because Methods 1 through 4 are also being referenced, clarify that the sampling time and sample volume apply to each Method 25A run.

III. Administrative Requirements

Under Executive Order 12866 (58 FR 51736, October 4, 1993), this action is not a ''significant regulatory action'' and is, therefore, not subject to review by the Office of Management and Budget (OMB). Because EPA 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, it is not subject to the regulatory flexibility 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) (Public Law 104–4). 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 the UMRA. This action also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13175 (63 FR 67249, November 6, 2000). This action 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 also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant.

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (Pub. L. 104–113; 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory and procurement activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA is not proposing/adopting any voluntary consensus standards in this action.

This technical correction action does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). In issuing these technical corrections, EPA has taken the 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). The EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of these technical corrections in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings' issued under the Executive Order. These technical corrections do not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The EPA's compliance with these statutes and Executive Orders for the underlying rule is discussed in the NESHAP for chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills.

The Congressional Review Act (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 Congressional Review Act if the agency makes a good cause finding that notice and public procedure is 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 therefor, and established an effective date of July 19, 2001. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Pulp and paper mills.

Dated: June 8, 2001.

Robert D. Brenner,

Acting Assistant Administrator for Air and Radiation.

For the reasons set out in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

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

Subpart MM—National Emission Standards for Hazardous Air Pollutants for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills

2. Section 63.863 is amended by revising paragraph (a) and (b) to read as follows:

§ 63.863 Compliance dates.

(a) The owner or operator of an existing affected source or process unit must comply with the requirements in this subpart no later than March 13, 2004.

(b) The owner or operator of a new affected source that has an initial startup date after March 13, 2001 must comply with the requirements in this subpart immediately upon startup of the affected source, except as specified in § 63.6(b).

* * * * *

3. Section 63.865 is amended by:

a. Revising paragraph (a) introductory text;

b. Removing paragraphs (a)(3) and (4);

c. Revising paragraphs (b) introductory text, (b)(2), and (b)(4);

d. Adding paragraphs (b)(5) and (6);

e. Revising paragraph (c) introductory text; and

f. Revising paragraph (d) introductory text.

The revisions and additions read as follows:

§ 63.865 Performance test requirements and test methods.

(a) The owner or operator of a process unit seeking to comply with a PM emission limit under § 63.862(a)(1)(ii)(A) must use the procedures in paragraphs (a)(1) and (2) of this section:

* * * * *

(b) The owner or operator seeking to determine compliance with § 63.862(a) or (b) must use the procedures in paragraphs (b)(1) through (6) of this section.

* * * * *

(2) For sources complying with paragraph (a) or (b) of § 63.862, the PM concentration must be corrected to the appropriate oxygen concentration using Equation 7 of this section as follows:

$$C_{corr} = Cmeas \times (21 - X)/(21 - Y) \quad \text{(Eq. 7)}$$

Where:

C_{corr} = the measured concentration corrected for oxygen, g/dscm (gr/dscf).

C_{meas} = the measured concentration uncorrected for oxygen, g/dscm (gr/dscf).

X = the corrected volumetric oxygen concentration (8 percent for kraft or soda recovery furnaces and sulfite combustion units and 10 percent for kraft or soda lime kilns).

Y = the measured average volumetric oxygen concentration.

* * * * *

(4) For purposes of complying with of § 63.862(a)(1)(ii)(A), the volumetric gas flow rate must be corrected to the appropriate oxygen concentration using Equation 8 of this section as follows:

$$Q_{corr} = Qmeas \times (21 - Y)/(21 - X) \quad \text{(Eq. 8)}$$

Where:

Q_{corr} = the measured volumetric gas flow rate corrected for oxygen, dscm/min (dscf/min).

Q_{meas} = the measured volumetric gas flow rate uncorrected for oxygen, dscm/min (dscf/min).

Y = the measured average volumetric oxygen concentration.

X = the corrected volumetric oxygen concentration (8 percent for kraft or soda recovery furnaces and 10 percent for kraft or soda lime kilns).

(5) For purposes of selecting sampling port location and number of traverse points, determining stack gas velocity and volumetric flow rate, conducting gas analysis, and determining moisture content of stack gas, Methods 1 through 4 in appendix A of 40 CFR part 60 must be used.

(6) Process data measured during the performance test must be used to determine the black liquor solids firing rate on a dry basis and the CaO production rate.

(c) The owner or operator seeking to determine compliance with the gaseous organic HAP standard in § 63.862(c)(1) without using an NDCE recovery furnace equipped with a dry ESP system must use Method 308 in appendix A of this part, as well as Methods 1 through 4 in appendix A of part 60 of this chapter. The sampling time and sample volume for each Method 308 run must be at least 60 minutes and 0.014 dscm (0.50 dscf), respectively.

* * * * *

(d) The owner or operator seeking to determine compliance with the gaseous organic HAP standards in § 63.862(c)(2) for semichemical combustion units must use Method 25A, as well as Methods 1 through 4, in appendix A of part 60 of this chapter. The sampling time for each Method 25A run must be at least 60 minutes.

* * * * *

[FR Doc. 01–17559 Filed 7–18–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301146 FRL–6793–8]

RIN 2070–AB78

Extension of Tolerances for Emergency Exemptions (Multiple Chemicals)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the pesticides listed in Unit II. of the **SUPPLEMENTARY INFORMATION**. These actions are in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of these pesticides. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA.

DATES: This regulation is effective July 19, 2001. Objections and requests for hearings, identified by docket control number OPP–301146, must be received by EPA on or before August 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by

mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the **SUPPLMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301146 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: See the listing below for the name of a specific contact person. The following information applies to all contact persons: Emergency Response Team, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9366.

Pesticide	CFR cite	Contact person/e-mail address
Avermectin	40 CFR 180.449	Beth Edwards/edwards.beth@epa.gov
Paraquat Dimethomorph Propamocarb hydrochloride Cymoxanil	40 CFR 180.205 40 CFR 180.493 40 CFR 180.499 40 CFR 180.503	Libby Pemberton/pemberton.libby@epa.gov
Fenbuconazole	40 CFR 180.480	Shaja R. Brothers/brothers.shaja@epa.gov
Fluroxypyr 1-Methylheptyl Ester	40 CFR 180.535	Andrew Ertman/ertman.andrew@epa.gov
Ethalfluralin Propiconazole Myclobutanil Tebuconazole Tebufenozide Imazamox Tetraconazole	40 CFR 180.416 40 CFR 180.434 40 CFR 180.443 40 CFR 180.474 40 CFR 180.482 40 CFR 180.508 40 CFR 180.557	Barbara Madden/madden.barbara@epa.gov

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table 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. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180 _0 0.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301146. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA published final rules in the **Federal Register** for each chemical/commodity listed below. The initial issuance of these final rules announced that EPA, on its own initiative, under section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) was establishing time-limited tolerances.

EPA established the tolerances because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Such tolerances can be established without providing notice or time for public comment.

EPA received requests to extend the use of these chemicals for this year's growing season. After having reviewed these submissions, EPA concurs that emergency conditions exist. EPA

assessed the potential risks presented by residues for each chemical/commodity. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18.

The data and other relevant material have been evaluated and discussed in the final rule originally published to support these uses. Based on that data and information considered, the Agency reaffirms that extension of these time-limited tolerances will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerances are extended until the date listed below. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (CFR). Although these tolerances will expire and are revoked on the date listed, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on the commodity after that date will not be unlawful, provided the residue is present as a result of an application or use of a pesticide at a time and in a manner that was lawful under FIFRA, the tolerance was in place at the time of the application, and the residue does not exceed the level that was authorized by the tolerance. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on these pesticides indicate that the residues are not safe.

Tolerances for the use of the following pesticide chemicals on specific commodities are being extended:

1. *Paraquat*. EPA has authorized under FIFRA section 18 the use of paraquat on green peas grown for seed and dry peas for control of weeds in Idaho, North Dakota, and Oregon. This regulation extends a time-limited tolerance for residues of the herbicide/desiccant/defoliant paraquat (1,1'-dimethyl-4,4'-bipyridinium-ion) derived from application of either the bis (methyl sulfate) or the dichloride salt (both calculated as the cation) in or on dry peas at 0.3 parts per million (ppm) for an additional 25½ month–period. This tolerance will expire and is revoked on December 31, 2003. A time-limited tolerance was originally published in the **Federal Register**on August 29, 1997 (62 FR 45748) (FRL–5739–8).

2. *Ethalfluralin*. EPA has authorized under FIFRA section 18 the use of ethalfluralin on canola for control of kochia in Montana, Minnesota, and North Dakota. This regulation extends a time-limited tolerance for residues of the herbicide ethalfluralin *N*-ethyl- *N*-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine in or on canola at 0.05 ppm for an additional 2–year period. This tolerance will expire and is revoked on Decmber 31, 2003. A time-limited tolerance was originally published in the **Federal Register** on December 17, 1997 (62 FR 66008) (FRL–5756–4).

3. *Propiconazole*. EPA has authorized under FIFRA section 18 the use of propiconazole on: cranberries for control of cottonball disease in Washington and Wisconsin; and dry beans for the control of rust in Minnesota and North Dakota. This regulation extends time-limited tolerances for combined residues of the fungicide propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolite determined as 2,4-dichlorobenzoic acid in or on cranberries at 1.0 ppm, dry beans at 0.5 ppm, dry bean forage at 8 ppm, and dry bean hay at 8 ppm for an additional 2–year period. These tolerances will expire and are revoked on December 31, 2003. A time-limited tolerance for cranberries was originally published in the **Federal Register** on April 11, 1997 (62 FR 17710) (FRL–5600–5). Time-limited tolerances for dry beans, dry bean forage and dry bean hay were originally published in the **Federal Register** on June 13, 1997 (62 FR 32224) (FRL–5718–8).

4. *Myclobutanil*. EPA has authorized under FIFRA section 18 the use of myclobutanil on hops for control of powdery mildew in Idaho, Oregon and Washington; on artichokes to control powdery mildew in California; and on peppers (bell and non-bell) to control powdery mildew in Califonia and New Mexico. This regulation extends a time-limited tolerance for residues of the fungicide myclobutanil in or on hop cones, dried at 5.0 ppm for an additional 2–year period. This tolerance will expire and is revoked on December 31, 2003. A time-limited tolerance was originally published in the **Federal Register** on July 10, 1998 (63 FR 37289) (FRL–5798-6). This regulation also extends time-limited tolerances for residues of myclobutanil in or on artichoke at 1.0 ppm and peppers (bell and non-bell) at 1.0 ppm for an additional 11–month period. These tolerances will expire and are revoked on June 30, 2003. Time-limited tolerances were originally published in the **Federal Register** on September 16, 1998 (63 FR 49472) (FRL–6025–1).

5. *Avermectin*. EPA has authorized under FIFRA section 18 the use of avermectin on basil for control of leafminers in California. This regulation extends a time-limited tolerance for residues of the miticide avermectin B1 and its delta–8,9–isomer in or on basil at 0.05 ppm for an additional 2–years and 5–months. This tolerance will expire and is revoked on December 31, 2003. A time-limited tolerance was originally published in the **Federal Register** on August 19, 1997 (62 FR 1466) (FRL–5737–1).

6. *Tebuconazole*. EPA has authorized under FIFRA section 18 the use of tebuconazole on hops for control of powdery mildew in Idaho, Oregon and Washington. This regulation extends a time-limited tolerance for residues of the fungicide tebuconazole; alpha-[2-(4-chlorophenyl)-ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol in or on hops at 4.0 ppm for an additional 2–year period. This tolerance will expire and is revoked on December 31, 2003. A time-limited tolerance was originally published in the **Federal Register** on December 2, 1998 (63 FR 66449) (FRL–6036–3).

7. *Fenbuconazole*. EPA has authorized under FIFRA section 18 the use of (alpha-[2-4-chlorophenyl)-ethyl]alpha-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile on grapefruit for control of greasy spot in Florida. This regulation extends time-limited tolerances for combined residues of the fungicide (alpha-[2-4-chlorophenyl)-ethyl]alpha-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile and its metabolites cis-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3H-furanone and trans-5(4-chlorophenyl)dihydro-3-phenyl-3-(1H1,2,4-triazole-1-ylmethyl-2-3H-furanone in or on whole grapefruit at 0.5 ppm, dried grapefruit pulp at 4.0 ppm, grapefruit oil at 35 ppm, and meat and meat by products of cattle, goats, hogs, horses, and sheep at 0.1 ppm for an additional 2–years period. These tolerances will expire and are revoked on December 31,2003. Time-limited tolerances were originally published in the **Federal Register** on July 26, 2000 (65 FR 45920) (FRL–6596–6).

8. *Tebufenozide*. EPA has authorized under FIFRA section 18 the use of tebufenozide on: grapes for the control of grape leaffolder and omnivorous leafroller in California; and longan and lychee for control of Lychee webworm in Florida. This regulation extends time-limited tolerances for residues of the insecticide tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide in or on grapes at 3 ppm and lychee and longan at 1.0 ppm for an additional 2–year period. These tolerances will expire and are

revoked on December 31, 2003. A time-limited tolerance was originally published for grapes in the **Federal Register** on July 6, 2000 (65 FR 41594) (FRL–6590–1). Time-limited tolerances were originally published for longan and lychee in the **Federal Register** on March 17, 1999 (64 FR 13088) (FRL–6065–2).

9. *Dimethomorph*. EPA has authorized under FIFRA section 18 the use of dimethomorph on squash, cantaloupe, watermelon, and cucumber for control of phytophthora capsici in Delaware, Illinois, Michigan, and Wisconsin. This regulation extends time-limited tolerances for residues of the fungicide dimethomorph in or on squash, cantaloupe, watermelon, and cucumber at 1.0 ppm for an additional 2–year, 3–month period. These tolerances will expire and are revoked on December 31, 2003. Time-limited tolerances were originally published in the **Federal Register** on February 18, 1998 (63 FR 8134) (FRL–5767–8).

10. *Propamocarb hydrochloride*. EPA has authorized under FIFRA section 18 the use of propamocarb hydrochloride on tomatoes for control of late blight in California. This regulation extends a time-limited tolerance for residues of the fungicide propamocarb hydrochloride in or on tomatoes, tomato puree and tomato paste at 0.5, 1.0, and 3.0 ppm, respectively, for an additional 25½ months. This tolerance will expire and is revoked on December 31, 2003. Time-limited tolerances were originally published in the **Federal Register** on May 16, 1997 (62 FR 26960) (FRL–5717–5).

11. *Cymoxanil*. EPA has authorized under FIFRA section 18 the use of cymoxanil on hops for control of downy mildew in Oregon. This regulation extends a time-limited tolerance for residues of the fungicide cymoxanil in or on dried hops at 1.0 ppm for an additional 25½–months. These tolerances will expire and are revoked on December 31, 2003. Time-limited tolerances were originally published in the **Federal Register** on December 2, 1998 (63 FR 66459) (FRL–6038–5).

12. *Imazamox*. EPA has authorized under FIFRA section 18 the use of imazamox on dry bean for control of various weeds in Wisconsin, Montana, Nebraska, Wyoming, Colorado, Minnesota and North Dakota. This regulation extends a time-limited tolerance for residues of the herbicide imazamox, 2-[4,5-dihydro-4-methyl-4-(1methylethyl)-5-oxo-1H-imidazol-2-yl]-5-methoxymethyl-3-pyridine-carboxylic acid, applied as the free acid or ammonium salt in or on dry beans at 0.05 ppm for an additional 2–year, 5–month period. This tolerance will expire and is revoked on December 31, 2003. A time-limited tolerance was originally published on July 14, 1999 (64 FR 37855) (FRL–6086–5).

13. *Fluroxypyr 1-methylheptyl ester*. EPA has authorized under FIFRA section 18 the use of fluroxypyr 1-methylheptyl ester on field corn and sweet corn for control of volunteer potatoes in Washington, Oregon, Idaho, and Wisconsin. This regulation extends time-limited tolerances for residues of the herbicide fluroxypyr 1-methylheptyl ester ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid, 1-methylheptyl ester and it's metabolite fluroxypyr in or on corn, sweet, K + CWHR at 0.05 ppm; corn, sweet, forage at 2.0 ppm; corn, sweet, stover at 2.5 ppm; corn, field, grain at 0.05 ppm; corn, field, forage at 2.0 ppm; corn, field, stover at 2.5 ppm for an additional 2–year, 1–month period. These tolerances will expire and are revoked on December 31, 2003. Time-limited tolerances were originally published in the **Federal Register** on August 5, 1998 (63 FR 41727) (FRL–6018–4).

14. *Tetraconazole*. EPA has authorized under FIFRA section 18 the use of tetraconazole on sugarbeets for control of cercospora leafspot in Michigan, Montana, Colorado, Nebraska, and Wyoming. This regulation extends time-limited tolerances for residues of the fungicide tetraconazole (+/-)-2-(2,4-dichlorophenyl)-3-(1H-1,2,4-triazol-1-yl) propyl 1, 1,2,2-tetrafluoroethyl ether in or on sugarbeets, and sugarbeet-related commodities, and for secondary residues of triazole on animal commodities from livestock fed sugarbeet by-products at 0.10 ppm on sugarbeet, 6.0 ppm in sugarbeet top, 0.20 ppm in sugarbeet dried pulp, 0.30 ppm in sugarbeet molasses, 0.050 ppm in milk, 0.030 ppm in cattle, meat and meat byproducts except kidney and liver, 0.20 ppm in kidney, 6.0 ppm in liver, and 0.60 ppm in fat for an additional 2–years. These tolerances will expire and are revoked on December 31, 2003. Time-limited tolerances were originally published in the **Federal Register** on December 6, 1999 (64 FR 68046) (FRL–6384–1).

III. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301146 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 20, 2001.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27).

Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you

must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim&epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit III.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301146, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket&epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IV. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or 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). 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); or OMB review or any other Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established under FFDCA section 408(l)(6) in response to an exemption under FIFRA section 18, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, 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.'' This rule will not have substantial direct effects on tribal governments, 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 in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

V. Submission to Congress and the Comptroller General

The Congressional Review Act, 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. 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 this final

rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: June 29,2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

§ 180.205 [Amended]

2. In § 180.205, in the table to paragraph (b), amend the entry for peas (dry) by revising the expiration/revocation date '' 11/15/01'' to read ''12/31/03.''

§ 180.416 [Amended]

3. In § 180.416, in the table to paragraph (b), amend the entry for canola by revising the expiration/revocation date ''12/31/01'' to read ''12/31/03.''

§ 180.434 [Amended]

4. In § 180.434, in the table to paragraph (b), amend the entries for cranberries; dry beans; dry bean forage; and dry bean hay by revising the expiration/revocation date ''12/31/01'' to read ''12/31/03.''

§ 180.443 [Amended]

5. In § 180.443, in the table to paragraph (b), amend the entries for hop cones, dried by revising the expiration/revocation date ''12/31/01'' to read ''12/31/03'' and amend the entries for artichoke and peppers (bell and non-bell) by revising the expiration/revocation date ''7/31/02'' to read ''6/30/03.''

§ 180.449 [Amended]

6. In § 180.449, in the table to paragraph (b), amend the entry for basil by revising the expiration/revocation date ''7/31/01'' to read ''12/31/03.''

§ 180.474 [Amended]

7. In § 180.474, in the table to paragraph (b), amend the entry for hops by revising the expiration/revocation date ''12/31/01'' to read ''12/31/03.''

8. In § 180.480, the table to paragraph (b), by revising the following entries:

§ 180.480 Fenbuconazole; tolerance for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/revocation Date
*	*	*
Cattle mbyp	0.01	12/31/03
Cattle meat	0.01	12/31/03
*	*	*
Goats, mbyp	0.01	12/31/03
Goats, meat	0.01	12/31/03
Grapefruit ..	0.5	12/31/03
Grapefruit pulp, dried	4.0	12/31/03
Grapefruit oil	35	12/31/03
*	*	*
Hogs, mbyp	0.01	12/31/03
Hogs, meat	0.01	12/31/03
*	*	*
Horses, mybp	0.01	12/31/03
Horses, meat	0.01	12/31/03
*	*	*
Sheeps, mybp	0.01	12/31/03
Sheeps, meat	0.01	12/31/03

* * * * *

§ 180.482 [Amended]

9. In § 180.482, in the table to paragraph (b), amend the entries for grapes; longan; and lychee by revising the expiration/revocation date ''12/31/01'' to read ''12/31/03''

§ 180.493 [Amended]

10. In § 180.493, in the table to paragraph (b), amend the entries for cantaloupe; cucumber; squash; and watermelon by revising the expiration/revocation date ''9/30/01'' to read ''12/31/03.''

§ 180.499 [Amended]

11. In § 180.499, in the table to paragraph (b), amend the entries for tomatoes; tomato paste; and tomato puree by revising the expiration/revocation date ''11/15/01'' to read ''12/31/03.''

§ 180.503 [Amended]

12. In § 180.503, in the table to paragraph (b), amend the entries for hops, dried, by revising the expiration/revocation date ''10/15/01'' to read ''12/31/03.''

§ 180.508 [Amended]

13. In § 180.508, in the table to paragraph (b), amend the entry for beans, dry by revising the expiration/revocation date ''7/15/01'' to read ''12/31/03.''

14. In § 180.535, the table to paragraph (b), is revised to read as follows:

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

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/revocation date
Corn, field, forage	2.0	12/31/03
Corn, field, grain	0.05	12/31/03
Corn, field, stover	2.5	12/31/03
Corn, sweet, forage	2.0	12/31/03
Corn,sweet, K + CWHR ...	0.05	12/31/03
Corn, sweet, stover	2.5	12/31/03

* * * * *

15. In § 180.557, the table to paragraph (b), is revised to read as follows:

§ 180.557 Tetraconazole; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/revocation date
Beet, sugar, dried pulp	0.20	12/31/03
Beet, sugar, molasses	0.30	12/31/03
Beet, sugar, roots	0.10	12/31/03
Beet, sugar, tops	6.0	12/31/03
Cattle, fat ..	0.60	12/31/03
Cattle, kidney	0.20	12/31/03
Cattle, liver	6.0	12/31/03
Cattle, meat	0.030	12/31/03

Commodity	Parts per million	Expiration/revocation date
Cattle, meat by-products; except kidney and liver	0.030	12/31/03
Milk	0.050	12/31/03

* * * * *

[FR Doc. 01–18099 Filed 7–18–01; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–1595; MM Docket No. 99–358; RM–9783 & RM–9838]

Radio Broadcasting Services; Burnet, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel 240A to Burnet, Texas, in response to a petition filed by Elgin FM Limited Partnership. *See* 64 FR 73463, December 30, 1999. The coordinates for Channel 240A at Burnet are 30–51–05 NL and 98–17–35 WL. There is a site restriction 12.1 kilometers (7.5 miles) northwest of the community. Concurrence of the Mexican government has been received for this allotment. The counterproposal filed by Evant Radio Company (RM–9838) for Evant, Texas, has been withdrawn. The counterproposal filed by Buchanan Radioworks for an allotment at Buchanan Dam, Texas, has been dismissed. With this action, this proceeding is terminated. A filing window for Channel 204A at Burnet will not be opened at this time. Instead, the issue of opening this allotment for auction will be addressed by the Commission in a subsequent order.

DATES: Effective August 20, 2001.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 99–358, adopted June 27, 2001, and released July 6, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800, facsimile (202) 857–3805.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Channel 240A at Burnet.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 01–18053 Filed 7–18–01; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 223

[I.D. 062001A]

Exemption to No-entry Zone around Bogoslof Island, Alaska

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

ACTION: Notification of authorized exemption to the no-entry zone around Bogoslof Island, Alaska.

SUMMARY: Pursuant to regulations that establish protections for Steller sea lions, the Administrator, Alaska Region, NMFS, authorized a one-time exemption to the 3–nautical mile (nm) no-entry zone around Bogoslof Island for the sole purpose of retracing, to the extent practicable, the 1899 Harriman Alaska Expedition. These regulations allow an exemption to the no-entry zone provided that the activity is authorized by the Administrator, Alaska Region, NMFS, and if the activity will not have a significant adverse affect on Steller sea lions, the activity has been conducted historically or traditionally in the buffer zone, and there is no readily available and acceptable alternative site for the activity.

SUPPLEMENTARY INFORMATION: On April 6, 2001, the Alaska Regional Office, NMFS received a letter that introduced the project, ''The 1899 Harriman Alaska Expedition Retraced: A Century of Change'', and requested that NMFS allow the M/V Clipper Odyssey to visit Bogoslof Island, Alaska, including a landing. The original Harriman Expedition visited Bogoslof Island on July 8, 1899, and the current expedition is expected to be near Bogoslof Island in mid-August of 2001.

The Steller sea lion population throughout western Alaska has declined by 80 percent during the past 3 decades, and the decline continues, especially for the pup, juvenile and subadult components of the sea lion population. Due to the continuing decline, NMFS has prohibited the landing on this, and other significant rookeries in the Bering Sea and Aleutian Islands, and prohibited the entry of any vessel, with exceptions, within 3 nm of the rookeries, since the species was listed as threatened under the Endangered Species Act in 1990 (55 FR 12645, April 5, 1990). In 1997 the western population was reclassified as endangered due to the continued decline in numbers, especially among pups and subadults (62 FR 24345, May 5, 1997). Pup counts on some rookeries have declined by greater than 40 percent during the past decade. Steller sea lion population trends on Bogoslof Island are consistent with those of the rest of the sea lion's range.

The Administrator, Alaska Region, may authorize an exemption to the prohibition to enter buffer zones around rookeries provided that the activity will not have a significant adverse affect on Steller sea lions, the activity has been conducted historically or traditionally in the buffer zone, and there is no readily available and acceptable alternative site for the activity (50 CFR 223.202 (b)(5)). There is no indication that a one-time entry into the buffer zone around Bogoslof Island (but not landing on the island) would have a significant adverse affect on Steller sea lions. Further, given that the purpose of this activity is to retrace an expedition that has historical significance to the State of Alaska, a one-time pass by the island is consistent with the intent of the historical aspects of the ''Harriman Expedition Retraced'' and does not increase the likelihood of a significant impact to the endangered sea lions that currently occupy the island. However, the expedition anticipates being in the Bogoslof Island area during the Steller sea lion and northern fur seal pupping season, and landing on the island could

have a significant adverse impact on successful reproduction or pup-rearing.

In a letter dated June 22, 2001, the Administrator, Alaska Region, granted an exemption to the prohibitions on entering the no-entry area around Bogoslof Island so the expedition may make a one-time pass through the no-entry zone for the sole purpose of retracing, to the extent practicable, the historic Harriman Expedition. Condition of this exemption include (1) a prohibition to land on the island, (2) the expedition vessel is not allowed to operate within 1 nm of any point on the rookery, and (3) no one is allowed to enter within 500m of any point on the rookery by any means, such as an inflatable vessel. All other provisions of 50 CFR 223.202 apply.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: July 13, 2001.

Donald R. Knowles,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 01–18103 Filed 7–18–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 010112013–1013–01; I.D. 071301A]

Fisheries of the Exclusive Economic Zone Off Alaska; Shortraker and Rougheye Rockfish in the Central Regulatory Area of the Gulf of Alaska

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

ACTION: Closure.

SUMMARY: NMFS is prohibiting retention of shortraker and rougheye rockfish in the Central Regulatory Area of the Gulf of Alaska (GOA). NMFS is requiring that catch of shortraker and rougheye rockfish in this area be treated in the same manner as prohibited species and discarded at sea with a minimum of injury. This action is necessary because the allocation of the shortraker and rougheye rockfish 2001 total allowable catch (TAC) in this area has been achieved.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), July 15, 2001, until 2400 hrs, A.l.t., December 31, 2001.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for the Groundfish Fishery of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and CFR part 679.

The 2001 TAC allocation of shortraker and rougheye rockfish for the Central Regulatory Area was established as 930 metric tons (mt) by the Final 2001 Harvest Specifications and Associated Management Measures for the Groundfish Fisheries Off Alaska (66 FR 7276, January 22, 2001).

In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS, has determined that the allocation of the shortraker and rougheye rockfish TAC in the Central Regulatory Area of the GOA has been achieved. Therefore, NMFS is requiring that further catches of shortraker and rougheye rockfish in the Central Regulatory Area of the GOA be treated as prohibited species in accordance with § 679.21(b).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, finds that the need to immediately implement this action to prevent overharvesting the allocation of the shortraker and rougheye rockfish TAC in the Central Regulatory Area of the GOA constitutes good cause to waive the requirement to provide prior notice opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(3)(B) and 50 CFR 679.20(b)(3)(iii)(A), as such procedures would be unnecessary and contrary to the public interest. Similarly, the need to implement these measures in a timely fashion to prevent overharvesting the allocation of the shortraker and rougheye rockfish TAC for the Central Regulatory Area of the GOA constitutes good cause to find that the effective date of this action cannot be delayed for 30 days. Accordingly, under 5 U.S.C. 553(d), a delay in the effective date is hereby waived.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: July 13, 2001.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–17985 Filed 7–13–01; 4:03 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 010112013–1013–01; I.D. 071301B]

Fisheries of the Exclusive Economic Zone Off Alaska; Sablefish by Vessels Using Trawl Gear in the Central Regulatory Area of the Gulf of Alaska

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

ACTION: Closure.

SUMMARY: NMFS is prohibiting retention of sablefish by vessels using trawl gear in the Central Regulatory Area of the Gulf of Alaska (GOA). NMFS is requiring that catch of sablefish by vessels using trawl gear in this area be treated in the same manner as prohibited species and discarded at sea with a minimum of injury. This action is necessary because the allocation of the sablefish 2001 total allowable catch (TAC) assigned to trawl gear in this area has been reached.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), July 16, 2001, until 2400 hrs, A.l.t., December 31, 2001.

FOR FURTHER INFORMATION CONTACT: Andrew Smoker, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for the Groundfish Fishery of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and CFR part 679.

The 2001 TAC allocation of sablefish assigned to trawl gear for the Central Regulatory Area was established as 1,082 metric tons (mt) by the Final 2001 Harvest Specifications and Associated Management Measures for the Groundfish Fisheries Off Alaska (66 FR 7276, January 22, 2001).

In accordance with § 679.20 (d)(2), the Administrator, Alaska Region, NMFS, has determined that the allocation of the sablefish TAC assigned to trawl gear in the Central Regulatory Area of the GOA has been reached. Therefore, NMFS is requiring that further catches of sablefish by vessels using trawl gear in the Central Regulatory Area of the GOA be treated as prohibited species in accordance with § 679.21 (b).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, finds that the need to immediately implement this action to prevent overharvesting the allocation of the sablefish TAC assigned to trawl gear in the Central Regulatory Area of the GOA constitutes good cause to waive the requirement to provide prior notice opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553 (b)(3)(B) and 50 CFR 679.20 (b)(3)(iii)(A), as such procedures would be unnecessary and contrary to the public interest. Similarly, the need to implement these measures in a timely fashion to prevent overharvesting the allocation of the sablefish TAC assigned to trawl gear for the Central Regulatory Area of the GOA constitutes good cause to find that the effective date of this action cannot be delayed for 30 days. Accordingly, under 5 U.S.C. 553 (d), a delay in the effective date is hereby waived.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: July 13, 2001.

Bruce C. Morehead

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–17986 Filed 7–13–01; 4:03 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 66, No. 139
Thursday, July 19, 2001

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 THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 25

[Docket No. 01–16]

RIN 1557–AB98

FEDERAL RESERVE SYSTEM

12 CFR Part 228

[Regulation BB; Docket No. R–1112]

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 345

RIN 3064–AC50

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 563e

[Docket No. 2001–49]

RIN 1550–AB48

Community Reinvestment Act Regulations

AGENCIES: Office of the Comptroller of the Currency, Treasury (OCC); Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); Office of Thrift Supervision, Treasury (OTS).

ACTION: Joint advance notice of proposed rulemaking.

SUMMARY: The OCC, Board, FDIC, and OTS (collectively, ''we'' or ''the agencies'') are beginning a review of our Community Reinvestment Act (CRA) regulations. This advance notice of proposed rulemaking (ANPR) seeks public comment on a wide range of questions as part of our review. We also welcome comments discussing other aspects of the CRA regulations and suggesting ways to improve the efficacy of the regulations.

DATES: Comments must be received by October 17, 2001.

ADDRESSES: *OCC:* Please direct your comments to: Docket No. 01–16, Communications Division, Public Information Room, Mailstop 1–5, Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219. You can inspect and photocopy all comments received at that address. In addition, you may send comments by facsimile transmission to fax number (202) 874–4448, or by electronic mail to regs.comments@occ.treas.gov.

Board: Comments should refer to Docket No. R–1112 and should be mailed to Ms. Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551, or mailed electronically to regs.comments@federalreserve.gov. Comments addressed to Ms. Johnson may also be delivered to the Board's mailroom between 8:45 a.m. and 5:15 p.m., and to the security control room outside those hours. Both the mailroom and the security control room are accessible from the Eccles Building courtyard entrance, located on 20th Street between Constitution Avenue and C Street, NW. Members of the public may inspect comments in Room MP–500 of the Martin Building between 9:00 a.m. and 5:00 p.m. on weekdays.

FDIC: Mail: Written comments should be addressed to Robert E. Feldman, Executive Secretary, Attention: Comments/OES, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

Delivery: Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

Facsimile: Send facsimile transmissions to fax number (202) 898–3838.

Electronic: Comments may be submitted to the FDIC electronically over the Internet at http://www.fdic.gov/regulations/laws/publiccomments/index.html. The FDIC has included a page on its web site to facilitate the submission of electronic comments in response to this ANPR concerning the CRA regulations (the EPC site). The EPC site provides an alternative to the written letter and may be a more convenient way for you to submit your comments or suggestions concerning the ANPR to the FDIC. If you submit comments through the EPC site, your comments will receive the same consideration that they would receive if submitted in hard copy to the FDIC's street address. Like comments or suggestions submitted in hard copy to the FDIC's street address, EPC site comments will be made available in their entirety (including the commenter's name and address if the commenter chooses to provide them) for public inspection. The FDIC, however, will not use an individual's name or any other personal identifier of an individual to retrieve records or information submitted through the EPC site. You will be able to view the ANPR directly on the EPC site and provide written comments and suggestions in the spaces provided.

You may also electronically mail comments to comments@fdic.gov.

Public Inspection: Comments may be inspected and photocopied in the FDIC Public Information Center, Room 100, 801 17th Street, NW., Washington, DC 20429, between 9:00 a.m. and 4:30 p.m. on business days.

OTS: Mail: Send comments to Regulation Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, Attention Docket No. 2001–49.

Delivery: Hand deliver comments to the Guard's Desk, East Lobby Entrance, 1700 G Street, NW., from 9:00 a.m. to 4:00 p.m. on business days, Attention: Regulation Comments, Chief Counsel's Office, Attention Docket No. 2001–49.

Facsimiles: Send facsimile transmissions to FAX Number (202) 906–6518, Attention: Docket No. 2001–49.

E-Mail: Send e-mails to regs.comments@ots.treas.gov, Attention Docket No. 2001–49 and include your name and telephone number.

Public Inspection: Comments and the related index will be posted on the OTS Internet Site at http://www.ots.treas.gov. In addition, you may inspect comments at the Public Reference Room, 1700 G Street, NW., by appointment. To make an appointment for access, call (202) 906–5922, send an e-mail to public.info@ots.treas.gov, or send a facsimile transmission to (202) 906–7755. (Prior notice identifying the material you will be requesting will assist us in serving you.) Appointments will be scheduled on business days

between 10:00 a.m. and 4:00 p.m. In most cases, appointments will be available the next business day following the date a request is received.

FOR FURTHER INFORMATION CONTACT:

OCC: Karen Tucker, National Bank Examiner, Community and Consumer Policy Division, (202) 874–4428; Margaret Hesse, Special Counsel, Community and Consumer Law Division, (202) 874–5750; or Patrick Tierney, Attorney, Legislative & Regulatory Activities Division, (202) 874–5090, Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219.

Board: William T. Coffey, Senior Review Examiner, (202) 452–3946; Catherine M.J. Gates, Oversight Team Leader, (202) 452–3946; or Kathleen C. Ryan, Senior Attorney, (202) 452–3667, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

FDIC: Deanna Caldwell, Senior Policy Analyst, (202) 942–3366; Stephanie Caputo, Fair Lending Specialist (202) 942–3413; or Robert Mooney, Assistant Director, (202) 942–3378, Division of Compliance and Consumer Affairs; or Ann Johnson, Counsel, Legal Division, (202) 898–3573, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

OTS: Celeste Anderson, Policy Analyst, Compliance Policy, (202) 906–7990; Theresa A. Stark, Project Manager, Compliance Policy, (202) 906–7054; or Richard Bennett, Counsel (Banking and Finance), (202) 906–7409, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

Introduction

The Federal financial supervisory agencies are jointly undertaking a review of our CRA regulations, in fulfillment of our commitment to do so when we adopted the current regulations in 1995. See 60 FR 22156, 22177 (May 4, 1995). This ANPR marks the beginning of our assessment of the effectiveness of the regulations in achieving their original goals of (1) emphasizing in examinations an institution's actual performance in, rather than its process for, addressing CRA responsibilities; (2) promoting consistency in evaluations; and (3) eliminating unnecessary burden. Any regulatory changes that we determine to be necessary to improve the regulations' effectiveness will be made in a rulemaking after completion of this review.

With our initiation of this comprehensive review of the regulations, we seek to determine whether, and if so, how, the regulations should be amended to better evaluate financial institutions' performance under the CRA, consistent with the authority, mandate, and intent of the statute. We encourage comments from the industry and the public on all aspects of this ANPR, as well as other concerns regarding the regulations that may not be represented, in order to ensure a full discussion of the issues.

Background

In 1977, Congress enacted the CRA to encourage federally insured banks and thrifts to help meet the credit needs of their entire communities, including low-and moderate-income neighborhoods, consistent with safe and sound banking practices. 12 U.S.C. 2901 *et seq.* In the CRA, Congress determined that:

(1) Regulated financial institutions are required by law to demonstrate that their deposit facilities serve the convenience and needs of the communities in which they are chartered to do business;

(2) The convenience and needs of communities include the need for credit services as well as deposit services; and

(3) Regulated financial institutions have continuing and affirmative obligation[s] to help meet the credit needs of the local communities in which they are chartered. (12 U.S.C. 2901(a).) Further, Congress directed the agencies to assess an institution's record of meeting the credit needs of its entire community, and to consider that record when acting on an application for a deposit facility.

In 1993, we initiated a reform of our CRA regulations. The goal of the reform was to develop revised rules that would clarify how we would evaluate the performance of the institutions we supervise. It also was our goal to develop a new system of evaluating financial institutions' records with respect to CRA that would focus primarily on objective, performance-based assessment standards that minimize compliance burden while stimulating improved performance.

After holding seven public hearings and publishing two proposed rules, we jointly issued final rules (the ''regulations'') on May 4, 1995 (60 FR 22156). See 12 CFR 25, 228, 345, and 563e, implementing 12 U.S.C. 2901 *et seq.* We published related clarifying documents on December 20, 1995 (60 FR 66048) and May 10, 1996 (61 FR 21362). To assist financial institutions and the public, we have also provided interpretive guidance about the regulations in the form of questions and answers published in the **Federal Register**. *See* 65 FR 25088 (April 28, 2000).

Under the regulations, the agencies evaluate a financial institution through a performance-based examination, the scope of which is determined by the institution's size and business strategy. Large, retail-oriented institutions are examined using the lending, investment, and service tests. Small institutions are examined using a streamlined small institution test. Wholesale and limited purpose institutions are examined under a community development test. And, finally, all institutions have the option of being evaluated under a strategic plan. No matter which evaluation method is used, each institution's performance is evaluated in a ''performance context'' that examiners factor into their CRA evaluations. The performance context includes consideration of factors such as each institution's business strategy and constraints, as well as the needs of, and opportunities afforded by, the communities served.

As stated, our goal was to make CRA examinations more objective and performance-based. To this end, the regulations require large institutions to collect, report, and disclose data on small business, small farm and community development loans, as well as limited data about home mortgage lending outside metropolitan statistical areas (MSAs), if the institution is subject to the Home Mortgage Disclosure Act (HMDA).

Issues for Comment

A fundamental issue for consideration is whether any change to the regulations would be beneficial or is warranted. Industry representatives, community and consumer organization representatives, members of Congress, and the public have discussed the regulations with the agencies over the years, e.g., during examinations, in the application process, at conferences, and at other meetings. Some suggest that the regulations work reasonably well and that little or no change is necessary. Others suggest that more extensive changes may be needed to reflect the significant changes in the delivery of services and expansion of products offered by financial institutions as a result of new technologies and financial modernization legislation. Still others advise that regulatory changes are inherently burdensome, so the benefit of any change should be weighed against the cost of effecting the change.

The following discussion identifies some of the issues that may warrant our review. The discussion is by no means exhaustive of all the issues that could be raised or the viewpoints that could be expressed. Commenters are invited to respond to the questions presented and to offer comments or suggestions on any other issues related to the CRA regulations, including developments in the industry that may impact how we evaluate CRA performance in the future. The agencies also welcome suggestions on what, if any, other steps we might undertake instead of, or in addition to, revising the regulations.

1. Large Retail Institutions: Lending, Investment, and Service Tests

Large retail institutions are subject to the lending, investment, and service tests. These tests primarily consider such things as the number and dollar amount of loans, qualified investments, and services, and the location and recipients of these activities. The tests also call for qualitative consideration of an institution's activities, including whether, and to what extent, loans, investments, and services are responsive to community credit needs; whether and to what extent they are innovative, flexible, or complex activities; and, in the case of investments, the degree to which the investments are not routinely provided by private investors. Thus, the regulations attempt to temper their reliance on quantitative factors by requiring examiners to evaluate qualitative factors, because not all activities of the same numerical magnitude have equal impact or entail the same relative importance when undertaken by different institutions in different communities.

Nonetheless, because the tests first consider the number and dollar amount of loans, investments, or services, some are of the opinion that CRA evaluations have become simply a ''numbers game.'' They question whether the regulations strike the right balance between evaluation of the quantity and quality of CRA activities. They suggest, for example, that the regulations provide too little consideration for an institution's focus on smaller projects '' whether or not ''innovative'' '' that are particularly difficult to carry out, but are especially meaningful and responsive to the institution's community.

Institutions' CRA ratings reflect the principle that lending is the primary vehicle for meeting a community's credit needs. In the 1995 preamble to the regulations, the agencies published a ratings matrix for examiners to use when evaluating large retail institutions under the lending, investment, and service tests. Under this matrix, it is impossible for an institution to achieve a ''satisfactory'' rating overall unless it receives at least a ''low satisfactory'' rating on the lending test. The agencies continue to use this ratings matrix.

With respect to the emphasis placed on each category of an institution's activities, some question whether lending should be emphasized more than investments and services. They assert that a CRA evaluation should allow for adjustment of this emphasis in a manner that more nearly corresponds with the activities of the institution and the particular needs of its community. For example, they assert, if an institution does not significantly engage in retail lending and, therefore, makes few loans, the lending test should not receive more emphasis than the investment and service tests for that institution's CRA evaluation.

Others contend, however, that lending should always be stressed, because they believe that deposits derived from communities should be reinvested in those communities through loans. Still others assert that lending should be the *only* basis upon which institutions are evaluated.

Finally, with respect to the three tests, some have argued that an institution's record of providing services should be given more emphasis than it currently is given. Others assert that providing services is not relevant to assessing whether an institution is meeting the credit needs of its community.

• Do the regulations strike the appropriate balance between quantitative and qualitative measures, and among lending, investments, and services? If so, why? If not, how should the regulations be revised?

A. *Lending test.* The agencies evaluate an institution's lending performance by considering the number and amount of loans originated or purchased by the institution in its assessment area; the geographic distribution of its lending; characteristics, such as income level, of its borrowers; its community development lending; and its use of innovative or flexible lending practices to address the credit needs of low- or moderate-income individuals or geographies in a safe and sound manner.

One aspect of the lending test that some have raised with the agencies is that the regulations allow equal consideration for loan originations and purchases. Some assert that only loan originations should be considered in an institution's evaluation. Supporters of this position maintain that consideration of loan purchases does not encourage institutions to increase capital in their communities. Rather, they believe equal consideration may prompt institutions to buy and sell the same loans repeatedly to influence their CRA ratings. On the other hand, some contend that loan purchases free up capital to the selling institution, thus enabling it to make additional loans. Still others argue that both purchases and originations should be considered, but originations should be weighted more heavily because they require more involvement by the institution with the borrower.

A related issue focuses on how the agencies should treat secondary market activity. The regulations currently capture purchased loans under the lending test and purchased asset-backed securities under the investment test. Some find this distinction to be artificial, and propose that purchased loans and purchased asset-backed securities should be captured under the same test, although they differ on which test should be used.

In addition, some are concerned that the regulations generally seem to provide consideration of loans without regard to whether the lending activities are appropriate. They recommend that a CRA examination also should include consideration of whether certain loans contain harmful or abusive terms and, therefore, do not help to meet community credit needs.

• Does the lending test effectively assess an institution's record of helping to meet the credit needs of its entire community? If so, why? If not, how should the regulations be revised?

B. *Investment test.* The agencies evaluate large retail institutions' performance under the investment test based on the dollar amount of qualified investments, their innovativeness or complexity, their responsiveness to credit and community development needs, and the degree to which they are not routinely provided by private investors. The agencies included the investment test in CRA evaluations in recognition that investments, as well as loans, can help meet credit needs.

With respect to whether it is appropriate to evaluate institutions' investment activities, some suggest that investments by financial institutions are invaluable in helping to meet the credit needs of the institutions' communities, particularly in low- and moderate-income areas. Still others assert that the agencies should only consider investment activities to augment institutions' CRA ratings. In their view, although investments may help an institution to meet the credit needs of its community, particularly in low- and moderate-income areas, CRA ratings should be based primarily on lending

activity. Others state, however, that it is inappropriate for the agencies to evaluate investments under the CRA as a means of meeting credit needs.

The availability of qualified investments has also been an issue of concern to some. Although some have observed that since the regulations went into effect, the market of available CRA-related investments has grown and continues to grow, others assert that appropriate investment opportunities may not be available in their communities. Further, some of the retail institutions subject to the investment test have indicated that, in some cases, it has been difficult to compete for investment opportunities, particularly against much larger institutions.

In addition, some have raised concerns that the innovative and complex elements of the investment test lead to a constant demand to change programs, even where existing programs are successful, just to maximize CRA consideration. Others have asked the agencies to reduce the uncertainty of how investments will be evaluated in an examination.

• Does the investment test effectively assess an institution's record of helping to meet the credit needs of its entire community? If so, why? If not, how should the regulations be revised?

C. *Service test.* Under the service test, the agencies consider an institution's branch distribution among geographies of different income levels, its record of opening and closing branches, particularly in low- and moderate-income geographies, the availability and effectiveness of alternative systems for delivering retail banking services in low- and moderate-income geographies and to low- and moderate-income individuals, and the range of services provided in geographies of all income levels, as well as the extent to which those services are tailored to meet the needs of those geographies. The agencies also consider the extent to which the institution provides community development services and the innovativeness and responsiveness of those community development services.

The criteria for evaluating retail services have led to discussion on the test's effectiveness. Some argue that the service test depends too heavily on the provision of brick and mortar banking services, particularly when one considers that many services are now provided by telephone, mail or electronically. Others assert that brick and mortar banking facilities should be weighted heavily because they are necessary, especially in low- and moderate-income neighborhoods where consumers may not have access to electronic banking services. These issues have led some to propose that the evaluation should consider not only the delivery method and type of service, but also the effectiveness of the delivery method, i.e., the extent to which low- and moderate-income persons actually use the services offered. In addition, some have suggested that the test should provide more consideration for flexible and innovative deposit accounts.

As for community development services, such as providing technical assistance on financial matters to nonprofit organizations serving low- and moderate-income housing needs, some suggest that these services are not given adequate consideration. In particular, they state that community development services are often a critical component of delivering or supporting activities considered under the lending test. Some also argue, however, that there is no incentive for an institution to engage in what might be labor intensive endeavors because community development services are only a small component of its overall evaluation. Others suggest that community development services should be evaluated within the context of other community development activities, such as lending and investments, because evaluating them separately could result in artificial designations and may not give adequate consideration to the integral relationship among the activities. Still others suggest that the community development and retail services components should be combined. *See* related discussion in 1.D.

• Does the service test effectively assess an institution's record of helping to meet the credit needs of its entire community? If so, why? If not, how should the regulations be revised?

D. *Community development activities of large retail institutions.* Under the regulations, ''community development'' means affordable housing (including multifamily rental housing) for low- or moderate-income individuals; community services targeted to low- or moderate-income individuals; activities that promote economic development by financing small businesses and farms; and activities that revitalize or stabilize low- or moderate-income geographies.

The definition of ''community development'' has spurred discussion since the regulations were published. Some assert that the definition of ''community development'' is not broad enough to cover the full range of activities that should receive favorable consideration. For example, some indicate that many projects intended to revitalize or stabilize rural communities do not qualify under the current regulatory definition of community development because they are not located in low- or moderate-income geographies, as defined in the regulations. Others assert that the definition does not adequately value activities benefiting communities or projects involving persons with a mix of incomes.

Issues also have arisen with respect to the geographic location of an institution's community development activities. For large retail institutions, the agencies consider community development activities in their assessment areas or a broader statewide or regional area that includes their assessment areas. Some suggest that large retail institutions should receive full consideration for community development activities anywhere they are conducted, as long as the institutions have adequately addressed the needs of their assessment areas. They contend that such consideration should be similar to the consideration of community development activities given wholesale and limited purpose institutions that are evaluated under the community development test. Others express concern, however, that if retail institutions are given the opportunity to receive consideration for community development activities outside their assessment areas and the broader statewide or regional areas that include their assessment areas, such an opportunity may be interpreted as a requirement to serve these areas. Still others argue that allowing activities further afield to receive consideration would diminish institutions' incentives to serve their own communities.

As discussed above, the community development loans, qualified investments, and community development services of large retail institutions are considered separately under the lending, investment, and service tests, respectively. Some suggest this evaluation method leads institutions to be overly concerned with whether they have ''enough'' of each activity. They argue that all community development activities, whether loans, investments or services, should be evaluated in one separate test, rather than in the existing three tests. Under such a test, an institution would receive consideration for community development loans, investments, and services needed in its community, based on the opportunities that exist and the ability of the institution to respond.

• Are the definitions of ''community development'' and related terms

appropriate? If so, why? If not, how should the regulations be changed?

• Are the provisions relating to community development activities by institutions that are subject to the lending, investment, and service tests effective in assessing those institutions' performance in helping to meet the credit needs of their entire communities? If so, why? If not, how should the regulations be revised?

2. Small Institutions: The Streamlined Small Institution Evaluation

A ''small institution'' is defined as an institution with total assets of less than $250 million that is independent or is affiliated with a holding company with total bank and thrift assets of less than $1 billion as of the two preceding year ends. Some suggest that the asset thresholds for being considered a small institution are too low. Others assert that holding company assets are irrelevant—if a bank has less than $250 million in assets, it should be considered small even if it is affiliated with a large holding company. Still others suggest that holding company assets are relevant only if the holding company provides support for CRA activities or otherwise directs the CRA activities of an institution.

Small institutions are evaluated under a streamlined test that focuses primarily on lending. When evaluating a small institution, an agency considers its loan-to-deposit ratio; the percentage of loans in its assessment areas; its record of lending to borrowers of different income levels and businesses and farms of different sizes; the geographic distribution of its loans; and its record of taking action, if warranted, in response to written complaints about its performance in helping to meet credit needs in its assessment area(s).

The small institution performance standards generally have been favorably received. Some, however, express concerns that the small institution assessment method does not provide for adequate consideration of non-lending-related investments, retail-related services, or community development services. Others assert that the small institution performance standards do not adequately consider the activities small institutions are performing in their communities, particularly in highly competitive markets. Others say that the standards do not create a sufficient incentive for small institutions to seek out and make investments, provide new services, or strive for higher ratings. Some also argue that institutions evaluated under the streamlined method should not be eligible for an ''outstanding'' rating based on their lending activities alone—that a small institution should be engaged in making investments and providing services in order to receive a rating higher than satisfactory.

• Do the provisions relating to asset size and holding company affiliation provide a reasonable and sufficient standard for defining ''small institutions'' that are eligible for the streamlined small institution evaluation test? If so, why? If not, how should the regulations be revised?

• Are the small institution performance standards effective in evaluating such institutions' CRA performance? If so, why? If not, how should the regulations be revised?

3. Limited Purpose and Wholesale Institutions: The Community Development Test

The community development test is the evaluation method used for limited purpose and wholesale institutions. A limited purpose institution offers only a narrow product line (such as credit card or motor vehicle loans) to a regional or broader market and must request and receive designation as a limited purpose institution from its regulatory agency. A wholesale institution is not in the business of extending home mortgage, small business, small farm, or consumer loans to retail customers, and similarly must obtain a designation as a wholesale institution.

Some question whether the definitions of limited purpose and wholesale institutions are appropriate. For example, they ask whether the definition of limited purpose should be expanded to a limited extent to capture retail institutions that offer more than a narrow product line on a regional or national basis.

Under the community development test, the agencies consider the number and amount of community development loans, qualified investments, or community development services; the use of innovative or complex qualified investments, community development loans, or community development services and the extent to which the investments are not routinely provided by private investors; and the institution's responsiveness to credit and community development needs. Wholesale and limited purpose institutions may receive consideration for community development activities outside of their assessment areas (or a broader statewide or regional area that includes their assessment areas) as long as they have adequately addressed the needs of their assessment areas.

Some question whether the community development test for wholesale and limited purpose institutions is as rigorous as the lending, investment, and service tests are for large retail institutions. Others suggest that the community development test may be an appropriate test not only for limited purpose and wholesale institutions, but also for other types of institutions, such as branchless institutions that provide a broad range of retail services nationwide by telephone, mail, or electronically. Still others assert that the community development test may be an appropriate test for any retail institution.

• Are the definitions of ''wholesale institutions'' and ''limited purpose institution'' appropriate? If so, why? If not, how should the regulations be revised?

• Does the community development test provide a reasonable and sufficient standard for assessing wholesale and limited purpose institutions? If so, why? If not, how should the regulations be revised?

• Would the community development test provide a reasonable and sufficient standard for assessing the CRA record of other insured depository institutions, including retail institutions? If so, why and which ones, and how should the regulations be revised? If not, why not?

4. Strategic Plan

The agencies developed the strategic plan option to provide institutions with more flexibility and certainty regarding what aspects of their performance will be evaluated and what quantitative and qualitative measures will be applied. To exercise this option, an institution must informally seek suggestions from the public while developing its plan, solicit formal public comment on its plan, and submit the plan to its regulatory agency (along with any written comments received from the public and an explanation of any changes made to the plan in response to those public comments).

To be approved by an agency, a CRA strategic plan must have measurable goals and address how the institution plans to meet the credit needs of its assessment area, in particular, low- and moderate-income geographies and individuals, through lending, investments, and services, as appropriate. Although strategic plans should generally emphasize lending goals, the rule allows institutions the flexibility to choose a different emphasis, as necessary, given their business strategy and the needs of their community.

Strategic plans must contain goals that, if met, would constitute ''satisfactory'' performance. An

institution may also include goals that would constitute ''outstanding'' performance. Upon examination, an institution that substantially achieves its goals under its approved plan will receive the rating attributed to those goals in its plan.

Only a few institutions have used the strategic plan option. These institutions indicate that they prefer the certainty provided by having a strategic plan. On the other hand, others have said that they have chosen not to pursue this option because of concern about the public nature of the process and the plan itself, including concern that their competitors might obtain information about their business strategy. Some indicate that they have found it difficult to develop a strategic plan with measurable goals. These concerns have led some to suggest that the strategic plan option should be reformed, while others suggest that it should be eliminated.

Some suggest that a strategic plan allows non-traditional institutions, such as institutions that provide a wide range of products nationwide via the Internet or through other non-branch-based delivery systems, to set performance goals that better reflect the markets they serve. Some suggest that a strategic plan should be mandatory for certain non-traditional institutions, particularly an institution for which the vast majority of retail lending activity occurs outside of its assessment area as defined by the regulation. Others suggest that the strategic plan option could be used to blend existing assessment methods for different business lines within one institution, for example, in the context of a bank with a retail branch network in one part of the country and wholesale operations in another, or an Internet presence nationally.

• Does the strategic plan option provide an effective alternative method of evaluation for financial institutions? If so, why? If not, how should the regulations be revised?

5. Performance Context

The regulations provide that an institution's performance under the tests and standards is evaluated in the context of information about the institution, its community, its competitors, and its peers. Such information may include, among other things, demographic data about the institution's assessment areas; the institution's product offerings and business strategy; lending, investment, and service opportunities in its assessment areas; any institutional capacity and constraints; and information about the institution's past performance and the performance of similarly situated lenders.

Some assert that performance context provides a means to evaluate the qualitative impact of an institution's activities in a community, striking the right balance between the quantity and quality of an institution's activity. The appropriate information helps to assess the responsiveness of an institution's activities to community credit needs. Performance context may also provide insight into whether an activity involving a lower dollar amount could meet community needs to a greater extent than an activity with a higher dollar amount, but with less innovation, complexity, or impact on the community.

Others assert that consideration of a performance context may create uncertainty about what activities will be considered and how they will be weighted during a CRA examination. They contend that more specific and quantifiable measures are needed to understand CRA evaluations more fully, despite the quantitative and qualitative factors outlined in the regulations and interagency guidance.

On the other hand, others have raised concerns that prescribing performance ratios for institutions would result in rigid performance requirements, and thereby eliminate the advantages of a performance context analysis. They maintain that the performance context provides examiners with the latitude needed to conduct a meaningful evaluation. They contend this latitude is important given the different types of institutions and communities, and the wide variety of business, market, economic, and other factors that can affect an institution's ability to respond to community credit needs.

• Are the provisions on performance context effective in appropriately shaping the quantitative and qualitative evaluation of an institution's record of helping to meet the credit needs of its entire community? If so, why? If not, how should the regulations be revised?

6. Assessment Areas

The regulations contain guidelines for institutions to use in defining their assessment areas. The assessment area is the geographic area in which the agencies will evaluate an institution's record of meeting the credit needs of its community. The regulations provide that an institution's assessment area should consist generally of one or more metropolitan statistical areas or one or more contiguous political subdivisions, and include geographies where the institution has its main office, branches, and deposit-taking ATMs, as well as surrounding geographies where the institution has originated or purchased a substantial portion of its loans. An institution may adjust the boundaries of its assessment area to include only the portion of a political subdivision that it can reasonably expect to serve. However, an institution's assessment area may not reflect illegal discrimination and may not arbitrarily exclude low- or moderate-income geographies, taking into account the institution's size and financial condition.

Some indicate that the assessment area delineation in the regulations has proven appropriate for most institutions. They assert that assessment areas are appropriately limited to the geographic areas around an institution's main office, branches, and deposit-taking ATMs. They contend that this is an appropriate and practical way to give focus to an institution's responsibility to help meet the credit needs of its community. Further, they contend that an institution is most familiar with the areas in which it is physically located and is in the best position to help meet credit needs in those areas. Still others are concerned about setting expectations on where institutions should be conducting their business if assessment areas were to include areas in which the institutions are not physically located.

On the other hand, some assert that the regulations' designation of assessment areas '' based upon the location of the main office, branches, and deposit-taking ATMs of an institution—ignores a variety of deposit acquisition and credit distribution channels used by an increasing number of institutions to serve the retail public, often reaching widely dispersed markets. They argue that these channels should be considered part of an institution's ''community.'' Others suggest that the regulations' approach to assessment area may create a disincentive for institutions to engage in community development activities in low- and moderate-income communities and rural areas where they have no physical presence and which are not part of their assessment areas.

To address these and other concerns, some recommend that institutions be required to delineate geographically defined assessment areas wherever they deliver retail banking services, whether or not they have physical deposit-gathering branches or ATMs in each locale. Others suggest that the assessment area should not be limited to metropolitan statistical areas (MSAs), but that the regulations should allow statewide and even national assessment areas. Some others suggest that

assessment areas without a geographical delimitation should be allowed, such as one based on a type of customer—similar to the way an institution that predominantly serves military personnel is permitted by the statute to delineate its entire deposit customer base as its assessment area. Finally, some propose that the agencies should create a distinct evaluation method with respect to the assessment area for institutions that gather deposits and deliver products and services without using deposit-taking branches or ATMs, for example, those institutions that use the Internet almost exclusively to gather deposits and deliver products.

• Do the provisions on assessment areas, which are tied to geographies surrounding physical deposit-gathering facilities, provide a reasonable and sufficient standard for designating the communities within which the institution's activities will be evaluated during an examination? If so, why? If not, how should the regulations be revised?

7. Activities of Affiliates

Under the lending, investment, and service tests and the community development test, an institution may elect to have activities of its affiliates considered as part of its own record of performance. An ''affiliate'' is defined as any company that controls, is controlled by, or is under common control with another company. Subsidiaries of financial institutions are considered affiliates under this definition.

Some assert that activities of affiliates, and in particular, subsidiaries of a financial institution, should always be considered in an institution's CRA evaluation. They contend that, because the regulations provide for consideration of affiliates' activities only at an institution's option, some institutions may book loans, make investments, and provide services for low- and moderate-income persons primarily in the institution, while offering other products and services more predominantly targeted to middle- and upper-income persons in their affiliates or by lending through consortia. Thus, they argue, institutions may be using their affiliates' activities to manipulate their CRA ratings. Others contend that if institutions can opt for consideration of affiliates' activities to enhance their CRA performance, their CRA performance should also be affected if their affiliates engage in abusive lending activities.

Others suggest that affiliate activities should be required to have a direct impact on an institution's assessment area. Still others assert that only the activities of an insured depository institution should be considered in its CRA evaluation. Affiliate activities should be irrelevant, they argue, when rating an institution's CRA performance and should not be considered, even at the option of the institution. On the other hand, others have indicated that the current treatment of affiliate activities is appropriate because the CRA applies only to insured depository institutions.

• Are the provisions on affiliate activities, which permit consideration of an institution's affiliates' activities at the option of the institution, effective in evaluating the performance of the institution in helping to meet the credit needs of its entire community, and consistent with the CRA statute? If so, why? If not, how should the regulations be revised?

8. Data Collection and Maintenance of Public Files

The regulations require large institutions to collect and report data on small business, small farm and community development lending, as well as limited data about home mortgage lending outside MSAs, if the institutions are subject to HMDA. The data requirements were designed to avoid undue data collection, reporting, and disclosure burden by: (1) Conforming data requirements to the extent possible with data already collected under HMDA, call reports, and thrift financial reports; (2) limiting data reporting to large institutions; and (3) making reporting of certain types of data optional.

Some question the agencies' authority to require collection and reporting of data under the CRA regulations. Others express concerns about the limitations of the data collected and reported. For example, small business and small farm data are aggregated at the census tract level, while community development loans are aggregated at the institution level. Still others question whether the collected and reported data are sufficiently detailed to be of use. Some also suggest that investment data, as well as data on lending, are necessary to properly evaluate institutions' performance under CRA.

Some indicate that collection of the required data and maintenance of a public file is burdensome and that very few interested parties ask to see the public files. However, others assert that institutions' public files provide valuable information for the public to use to monitor the extent to which they serve their communities.

• Are the data collection and reporting and public file requirements effective and efficient approaches for assessing an institution's CRA performance while minimizing burden? If so, why? If not, how should the regulations be revised?

Conclusion

With this ANPR, we seek input to assist us in determining whether and, if so, how the CRA regulations should be revised. We welcome comments on all aspects of the CRA regulations and encourage all interested parties to provide their views. Hearing from parties with diverse viewpoints will help us to determine the most appropriate way to approach the review of the regulations.

Executive Order 12866

OCC and OTS: The agencies do not know now whether they will propose changes to the CRA rules and, if so, whether these changes will constitute a significant regulatory action under the Executive Order. This ANPR neither establishes nor proposes any regulatory requirements. OCC and OTS have submitted a notice of planned regulatory action to OMB for review. Because this ANPR does not contain a specific proposal, information is not available with which to prepare an economic analysis. OCC and OTS will prepare a preliminary analysis if they proceed with a proposed rule that constitutes a significant regulatory action.

Accordingly, we solicit comment, information, and data on the potential effects on the economy of any changes to the CRA rule that the commenter may recommend. We will carefully consider the costs and benefits associated with this rulemaking.

Dated: July 11, 2001.

John D. Hawke, Jr.,

Comptroller of the Currency.

Dated: July 12, 2001.

Jennifer J. Johnson,

Secretary of the Board, Board of Governors of the Federal Reserve System.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, this 10th day of July, 2001.

Robert E. Feldman,

Executive Secretary.

Dated: July 10, 2001.

Ellen Seidman,

Director, Office of Thrift Supervision.

[FR Doc. 01–18033 Filed 7–18–01; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P; 6720–01–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 4

[Notice No. 924]

RIN 1512–AC29

Proposed Addition of New Grape Variety Names for American Wines (2000R–322P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Bureau of Alcohol, Tobacco, and Firearms (ATF) is proposing to add four new names to the list of prime grape variety names for use in designating American wines: Albariño, Alvarinho, Black Corinth, and Fiano.

DATES: Written comments must be received by September 17, 2001.

ADDRESSES: Send written comments to: Chief, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 50221, Washington, DC 20091–0221 (Attn: Notice No. 924).

FOR FURTHER INFORMATION CONTACT: Jennifer Berry, Bureau of Alcohol, Tobacco and Firearms, Regulations Division, 111 W. Huron Street, Room 219, Buffalo, NY, 14202–2301; Telephone (716) 551–4048.

SUPPLEMENTARY INFORMATION:

1. Background

Under the Federal Alcohol Administration Act (27 U.S.C. § 201 *et seq.*) (FAA Act), wine labels must provide ''the consumer with adequate information as to the identity and quality'' of the product. The FAA Act also requires that the information appearing on wine labels not mislead the consumer.

To help carry out these statutory requirements, ATF has issued regulations, including those that designate grape varieties. Under 27 CFR § 4.23(b) and (c), a wine bottler may use a grape variety name as the designation of a wine if not less than 75 percent of the wine (51 percent in the case of wine made from *Vitis labrusca* grapes) is derived from that grape variety. Under § 4.23(d), a bottler may use two or more grape variety names as the designation of a wine if all of the grapes used to make the wine are of the labeled varieties, and if the percentage of the wine derived from each grape variety is shown on the label.

Treasury Decision ATF–370 (61 FR 522), January 8, 1996, adopted a list of grape variety names that ATF has determined to be appropriate for use in designating American wines. The list of prime grape names and their synonyms appears at § 4.91, while additional alternative grape names temporarily authorized for use are listed at § 4.92. ATF believes the listing of approved grape variety names for American wines will help standardize wine label terminology, provide important information about the wine, and prevent consumer confusion.

ATF has received petitions proposing that new grape variety names be listed in § 4.91. Under § 4.93 any interested person may petition ATF to include additional grape varieties in the list of prime grape names. Information with a petition should provide evidence of the following:

- Acceptance of the new grape variety;
- The validity of the name for identifying the grape variety;
- That the variety is used or will be used in winemaking; and
- That the variety is grown and used in the United States.

For the approval of names of new grape varieties, the petition may include:

- A reference to the publication of the name of the variety in a scientific or professional journal of horticulture or a published report by a professional, scientific or winegrowers' organization;
- A reference to a plant patent, if patented; and
- Information about the commercial potential of the variety, such as the acreage planted and its location or market studies.

Section 4.93 also places certain eligibility restrictions on the approval of grape variety names. A name will not be approved:

- If it has previously been used for a different grape variety;
- If it contains a term or name found to be misleading under § 4.39; or
- If a name of a new grape variety contains the term ''Riesling.''

The Director reserves the authority to disapprove the name of a new grape variety developed in the United States if the name contains words of geographical significance, place names, or foreign words which are misleading under § 4.39.

2. Petitions

Petition for Albariño/Alvarinho

Havens Wine Cellars in Napa, California, has petitioned ATF proposing the addition of the name ''Albariño'' to the list of prime grape names approved for the designation of American wines. Albariño, a white *Vitis vinifera* grape, has been grown for centuries in Spain and Portugal, but is relatively new to the United States. In Portugal, the grape is known by the name ''Alvarinho.''

The petitioners state that Albariño has long been recognized in Europe and in academic communities. As evidence of this, the petitioners submitted the following supporting documents provided by Professor Carole Meredith of the Viticulture and Enology Department at the University of California at Davis (UC Davis):

- European Union Regulation 3201/90: This regulation permits the use of the name ''Albariño'' on labels of Spanish wines, and the name ''Alvarinho'' on labels of Portuguese wines.
- Two scientific papers from the *American Journal of Enology and Viticulture:* ''Effects of Grapevine Leafroll-Associated Virus 3 on the Physiology and Must of Vitis vinifera L. cv. Albariño Following Contamination in the Field,'' published in Volume 50, 1999, discusses a study conducted on Albariño grape vines, and ''Contribution of Saccharomyces and Non-Saccharomyces Populations to the Production of Some Components of Albariño Wine Aroma,'' published in Volume 47, 1996, describes a study conducted on Albariño musts.
- ''The Genetic Resources of Vitis'': This listing of international grape variety names and synonyms, published in 1988 by the German Federal Grape Breeding Institute, lists Alvarinho as the prime name for the grape varietal with Albariño as a synonym.
- An abstract for an article from the *Journal of the American Society for Horticultural Science:* ''Molecular marker analysis of Vitis vinifera 'Albariño' and some similar grapevine cultivars,'' published September 1998, describes a DNA analysis conducted on Albariño grapevines.

The petitioner also submitted several wine literature articles, from sources such as Wine Spectator and Wine Today, which mention Albariño/Alvarinho wine.

ATF contacted Professor Meredith and asked her if the name ''Alvarinho'' should be added to the list as a synonym of Albariño. She replied that both names are well established in Europe and are equally valid names for the grape. She stated that because the grape is relatively new to the U.S., she didn't know which name is most commonly used by U.S. winemakers.

She noted that UC Davis has an example of the grapevine in its collection and uses the name ''Alvarinho'', most likely because the plant originally came from Portugal.

Havens Wine Cellar reports that it has 2½ acres of Albariño in production, with the first crop picked in 1999. They also presented evidence that at least two other California wineries are also growing Albariño. ATF knows of a Virginia winery that is also growing the grape. The petitioner comments that American consumers are looking for new and exciting varietals and Albariño fills this niche.

Based on the evidence presented by the petitioner, ATF proposes the addition of this grape to the list of American grape variety names. Since the evidence indicates that both names are equally valid, ATF proposes to add the names ''Albariño'' and ''Alvarinho'' to § 4.91 as prime names and as synonyms.

Petition for Black Corinth

Hallcrest Vineyards in Felton, California, has petitioned ATF to include the grape variety Black Corinth on the list of prime grape names approved for the designation of American wines. Black Corinth grapes are widely grown in California, where the vast majority of them are dried into raisins and marketed under the name ''Zante Currant.''

As evidence of the grape's acceptance and use in California, Hallcrest Vineyards submitted the following statistical reports issued by the State of California:

- Final Grape Crush Report for the 1999 crop, issued by the California Department of Food and Agriculture.
- California Grape Acreage report for 1999, issued by the California Agricultural Statistics Service, in cooperation with the U.S. Department of Agriculture.

Both reports include statistical tables with the data broken down by grape varietal, including Black Corinth. According to Table 2 of the Grape Acreage report, there were 2,384 standing acres of Black Corinth planted in California in 1999. The petitioner states these tables are clear evidence that the grape is grown in California and is recognized by the California Department of Food and Agriculture.

Other documentation of the grape includes The Oxford Companion to Wine (Jancis Robinson, Oxford University Press, 1999), which states that Black Corinth is one of the most commonly used grape varieties in the world raisin industry, and has on occasion been used in winemaking. The Office International de la Vigne et du Vin, an international association for wine, officially recognizes the names ''Black Corinth'' and ''Zante Currant'' for the grape.

Hallcrest Vineyards states it has made a fruity, blush dessert wine from the Black Corinth grape. ATF is aware of at least one other winery using the grape to produce a table wine. Because the evidence satisfies the requirements of § 4.93, ATF proposes to add Black Corinth to the list of prime grape names in § 4.91. Because ATF feels that the name ''Zante Currant'' may mislead the consumer into thinking the wine is made from currants and not grapes, it is not proposing the name as a synonym. ATF, however, welcomes comments on this issue.

Petition for Fiano

United Distillers and Vintners North America, Inc. (UDV) has petitioned ATF for the addition of the name ''Fiano'' to the list of prime grape names approved for the designation of American wines. UDV owns three wineries in California—Beaulieu Vineyards, Glenn Ellen Carneros Winery, and Blossom Hill.

Fiano is a white varietal, long grown in the Campania region of Italy where it is used to produce the Denominazione di Origine Controllata wine Fiano di Avellino. According to information submitted by the petitioner, Fiano is an old grape with a history that can be traced back to the ancient Romans. An order for Fiano wine was placed in the register of the Holy Roman Emperor Frederick II (1215–1250), and Charles d'Anjou (1227–1285) was known to have planted 16,000 Fiano vines. Reference sources referring to the Fiano grape include The New Sotheby's Wine Encyclopedia (Tom Stevenson, DK Publishing, Inc., 1997) and The Oxford Companion to Wine (Jancis Robinson, Oxford University Press, 1999).

As evidence of the grape's use in the U.S., UDV has submitted a price list from Herrick Grapevines in St. Helena, California, listing Fiano in the grapevine inventory. According to this inventory, the Fiano was planted in 1997 and was obtained from Duarte Nursery in Modesto, California. UDV further states that Beaulieu Vineyard has produced two vintages of Fiano wine, and it has submitted evidence that at least three other California vineyards and one New York vineyard are also growing Fiano. The petitioner submitted a letter from Monterey Pacific, one of the California growers, stating that they've had five years of experience with Fiano, and find it to be a grape with distinctive varietal character.

Based on the evidence presented in the petition, ATF is proposing the Fiano grape for inclusion in § 4.91.

3. Public Participation

Who May Comment on This Notice?

ATF requests comments from all interested parties. We will carefully consider all comments we receive on or before the closing date. We will also carefully consider comments we receive after that date if it is practical to do so, but we cannot assure consideration for late comments. ATF specifically requests comments on the clarity of this proposed rule and how it may be made easier to understand.

Can I Review Comments Received?

Copies of the petitions and written comments in response to this notice of proposed rulemaking will be available for public inspection during normal business hours at: ATF Reference Library, Office of Liaison and Public Information, Room 6480, 650 Massachusetts Avenue, NW., Washington, DC 20226.

Will ATF Keep My Comments Confidential?

ATF cannot recognize any material in comments as confidential. All comments and materials may be disclosed to the public. If you consider your material to be confidential or inappropriate for disclosure to the public, you should not include it in the comments. We may also disclose the name of any person who submits a comment. A copy of this notice and all comments will be available for public inspection during normal business hours at: ATF Reference Library, Office of Liaison and Public Information, Room 6300, 650 Massachusetts Avenue, NW., Washington, DC 20226.

How do I Send Facsimile Comments?

You may submit comments of not more than three pages by facsimile transmission to (202) 927–8525. Facsimile comments must:

- Be legible.
- Reference this notice number.
- Be 8½″ × 11″ in size.
- Contain a legible written signature.
- Be not more than three pages.

We will not acknowledge receipt of facsimile transmissions. We will treat facsimile transmissions as originals.

How Do I Send Electronic Mail (E-mail) Comments?

You may submit comments by e-mail by sending the comments to *nprm@atfhq.atf.treas.gov.* You must follow these instructions. E-mail comments must:

• Contain your name, mailing address, and e-mail address.
• Reference this notice number.
• Be legible when printed on not more than three pages size.

We will not acknowledge receipt of e-mail. We will treat e-mail as originals.

How Do I Send Comments to the ATF Internet Web Site?

You may also submit comments using the comment form provided with the online copy of the proposed rule on the ATF Internet web site at http://www.atf.treas.gov/alcohol/rules/index.htm.

3. Regulatory Analyses and Notices

Does the Paperwork Reduction Act Apply to This Proposed Rule?

The provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this notice because no requirement to collect information is proposed.

How Does the Regulatory Flexibility Act Apply to This Proposed Rule?

It is hereby certified that this proposed regulation will not have a significant economic impact on a substantial number of small entities. This regulation will permit the use of new grape varietal names. No negative impact on small entities is expected. No new requirements are proposed. Accordingly, a regulatory flexibility analysis is not required.

Is This a Significant Regulatory Action as Defined by Executive Order 12866?

This is not a significant regulatory action as defined by Executive Order 12866. Therefore, a regulatory assessment is not required.

4. Drafting Information

The principal author of this document is Jennifer Berry, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 4

Advertising, Customs duties and inspection, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Trade practices, Wine.

Authority and Issuance

Accordingly, 27 CFR part 4, Labeling and Advertising of Wine, is amended as follows:

PART 4—[AMENDED]

Paragraph 1. The authority citation for part 4 continues to read as follows:

Authority: 27 U.S.C. 205.

Para. 2. Section 4.91 is amended by republishing the introductory text and by adding the names ''Albariño'', ''Alvarinho'', ''Black Corinth'', and ''Fiano'' in alphabetical order, to the list of prime grape names, to read as follows:

§ 4.91 List of approved prime names.

The following grape variety names have been approved by the Director for use as type designations for American wines. When more than one name may be used to identify a single variety of grape, the synonym is shown in parentheses following the prime name. Grape variety names may appear on labels of wine in upper or in lower case, and may be spelled with or without the hyphens or diacritic marks indicated in the following list.

Albariño (Alvarinho)

* * * * *

Alvarinho (Albariño)

* * * * *

Black Corinth

* * * * *

Fiano

* * * * *

Signed: May 24, 2001.

Bradley A. Buckles,

Director.

Approved: June 22, 2001.

Timothy E. Skud,

Acting Deputy Assistant Secretary (Regulatory, Tariff & Trade Enforcement).

[FR Doc. 01–17935 Filed 7–18–01; 8:45 am]

BILLING CODE 4810–13–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

RIN 1010–AC–82

Oil and Gas and Sulphur Operations in the Outer Continental Shelf—Document Incorporated by Reference—American Petroleum Institute's Specification 2C for Offshore Cranes

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule.

SUMMARY: MMS is proposing to incorporate by reference the Fifth Edition of the American Petroleum Institute's Specification for Offshore Cranes (API Spec 2C) into its regulations. MMS is proposing this action to establish a minimum design standard for new cranes installed on fixed platforms on the Outer Continental Shelf (OCS) and to require all existing cranes installed on OCS fixed platforms to be equipped with anti-two block safety devices. This proposed rule would ensure that OCS lessees use the best available and safest technologies for the design and construction of cranes used on the OCS.

DATES: We will consider all comments we receive by October 17, 2001. We will begin reviewing comments then and may not fully consider comments we receive after October 17, 2001.

ADDRESSES: Mail or hand-carry comments (three copies) to the Department of the Interior; Minerals Management Service; Mail Stop 4024; 381 Elden Street; Herndon, Virginia 20170–4817; Attention: Rules Processing Team (RPT). If you wish to e-mail comments, the RPT's e-mail address is: rules.comments@mms.gov. Reference API Spec 2C in your e-mail subject line. Include your name and return address in your e-mail message and mark your message for return receipt.

Mail or hand-carry comments with respect to the information collection burden of the proposed rule to the Office of Information and Regulatory Affairs; Office of Management and Budget; Attention: Desk Officer for the Department of the Interior (OMB control number 1010–NEW); 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wilbon Rhome, Industrial Specialist, Operations Analysis Branch, at (703) 787–1587 or Fax (703) 787–1555.

SUPPLEMENTARY INFORMATION: We use standards, specifications, and recommended practices developed by standard-setting organizations and the oil and gas industry as a means of establishing requirements for activities on the OCS. This practice, known as incorporation by reference, allows us to incorporate the provisions of technical standards into the regulations. The legal effect of incorporation by reference is that the material is treated as if it were published in the **Federal Register**. This material, like any other properly issued regulation, then has the force and effect of law. We hold operators/lessees accountable for complying with the documents incorporated by reference in our regulations. We currently incorporate by reference 85 private sector consensus standards into the offshore operating regulations.

The regulations at 1 CFR part 51 govern how we and other Federal

agencies incorporate various documents by reference. Agencies may only incorporate by reference through publication in the **Federal Register**. Agencies must also gain approval from the Director of the **Federal Register** for each publication incorporated by reference. Incorporation by reference of a document or publication is limited to the specific edition, supplement, or addendum cited in the regulations.

Crane Standards

The primary reason MMS is proposing to incorporate by reference API Spec 2C into its regulations is to establish detailed requirements for the design and construction of pedestal-mounted cranes for new and existing OCS fixed platforms.

API Spec 2C will:

a. Provide a uniform method of establishing rated loads for cranes.

b. Require lessees to equip all new and existing cranes installed on OCS fixed platforms with anti-two block safety devices.

c. Ensure that OCS lessees use the best available and safest technologies for design and construction of cranes for installation in the OCS.

We believe API Spec 2C will be an excellent companion document to API Recommended Practice 2D, a document incorporated into MMS regulations, which deals with the operation and maintenance of offshore cranes. API Spec 2C includes minimum requirements for equipment, materials, manufacturing procedures, and testing (both design and operational) that are not covered in API RP 2D. Incorporating API Spec 2C into the regulations would address a safety gap in our regulations and improve crane safety on the OCS.

The anti-two block safety device is installed on a crane to protect hoist ropes, structural components, and machinery from damage, that might occur when two sheave groups (e.g., load block and boom head) come into contact as the hoist cable is drawn in. This situation is dangerous because: (1) The load block can detach from the load line, falling and causing serious injury or possible loss of life or considerable property damage, or (2) the load block can be pulled through the boom head, putting the crane operator at risk. There are several forms of anti-two block protection that are available to the oil and gas industry. One such form of protection is the control override device used to stall the hoist drums where damage or loss of control would be the result. Other forms of protection are audible or visual proximity warning devices. These anti-two block safety devices may be used in addition to the control override device, or used independently of the control override device.

In the past, MMS has encouraged industry to equip all cranes operating on OCS fixed platforms with an anti-two block safety device regardless of age or specific use of the crane. MMS now believes that anti-two block safety devices must be used on all cranes installed on OCS fixed platforms. We are convinced that retrofitting existing cranes with the anti-two block safety devices will benefit the industry by increasing safety and reducing or eliminating crane incidents on the OCS. Industry shares our concern as evidenced by a recent safety alert issued by the International Association of Drilling Contractors, stating that anti-two block safety devices should be installed on all cranes because ''Having a safety device like this ensures that everything is in place to prevent a problem. The anti-two block safety devices for the crane boom is a protection device as is the crown protection device on the rig's drawworks. Both are very important to working safely.''

It should be noted that the proposed regulation requiring the retrofitting of existing cranes would provide a 1-year transition period. This would allow the industry adequate time to implement this change without causing undue hardships.

Recordkeeping Requirements

With the incorporation of API Spec 2C, we would include additional recordkeeping requirements in § 250.108, consistent with the specification. Current regulations require you to keep at the OCS facility for at least 2 years the inspection, testing, and maintenance records of cranes and other material-handling equipment. The proposed regulations expand this to include maintaining records on the design and construction of cranes, including installation records for any anti-two block safety devices. We are also requiring that all records on cranes be retained for the life of the crane at the fixed offshore platform, rather than a minimum of 2 years.

This proposed rule also updates § 250.108 to specifically include retaining training records on rigger personnel, as well as those for crane operators. This is consistent with the API Recommended Practice 2D, Fourth Edition, which is already incorporated by reference in our regulations under § 250.198.

We specifically solicit comments on the following questions:

(a) Will the addition of API Spec 2C to MMS's documents incorporated by reference increase safety and safe operations on the OCS?

(b) Are there other standards for offshore cranes that may be appropriate for MMS to incorporate as part of MMS's regulations?

(c) When should MMS require all cranes on OCS fixed platforms to be fully compliant with API Spec 2C?

(d) Is a 1-year transition period enough time for industry to comply with the change proposed in § 250.108(c)?

(e) Should MMS establish a requirement similar to the U.S. Coast Guard (USCG), which requires cranes to be installed according to an approved crane plan and inspected and load tested by an Agency-approved third party when the crane is installed?

(f) Should MMS require all new cranes for installation on OCS fixed platforms to have an API monogram on the nameplate of the crane as evidence of certification of the anti-two block safety device?

(g) Should a rental crane that is installed on OCS fixed platforms be considered a new crane and, therefore, be required to be fully compliant with API Spec 2C?

(h) Should MMS limit the type of anti-two block devices that are acceptable? What are the known failure rates of the different types?

(i) Should MMS consider an additional cost factor for retrofitting existing cranes with the anti-two block safety device (e.g., an associated cost for the amount of time a crane is expected to be out-of-service while it is being retrofitted)?

Procedural Matters

The specifications in the API Spec 2C document we propose to incorporate by reference are currently widely accepted industry standards. The USCG has already incorporated API Spec 2C into its regulations. All cranes manufactured after 1983 came equipped with the anti-two block safety devices, and most earlier model cranes have been retrofitted with the anti-two block safety devices. Therefore, this regulation's impact on the entire oil and gas offshore industry is minor.

Public Comment Procedure

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home addresses from the rulemaking record, which we will honor to the extent allowable by law.

There may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses available for public inspection in their entirety. We will summarize written responses to this notice and address them in the preamble of the final rule. All comments will become a matter of public record.

Regulatory Planning and Review (Executive Order 12866)

This document is not a significant rule and is not subject to review by the Office of Management and Budget (OMB) under Executive Order 12866.

(1) This rule will not have an annual economic effect of $100 million or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. A cost-benefit and economic analysis is not required. The major purpose for this proposed rule is to establish a minimum design standard for new cranes installed on fixed platforms on the OCS, and to address an increase in accidents for those cranes that are not equipped with anti-two block safety devices. This rule also proposes to require lessees to equip all existing cranes installed on OCS fixed platforms with anti-two block safety devices. Since API Spec 2C has already been accepted as an industry standard in most of the offshore community, including the USCG, the impact of this regulation on the entire industry is minor. Therefore, the associated costs to equip the remaining cranes, not previously retrofitted, with anti-two block safety devices will be minor. Based on our experience and information in MMS's Technical Information Management System, we estimate that about 5 percent (or a total of not more than 200) of the 4,000 cranes located on the OCS will need to be retrofitted with the anti-two block safety device. We estimate that this will cost approximately $4,000 per retrofit, for a total cost of $800,000.

(2) This proposed rule will not create inconsistencies with other agencies' actions. This rule will not affect how lessees or operators interact with other agencies.

(3) This proposed rule will not affect entitlements, grants, user fees, loan programs, or their recipients. The rule only deals with the proposed action to incorporate by reference the API Spec 2C into our regulations.

(4) This proposed rule will not raise novel legal or policy issues. The proposed rule does involve a new policy issue, to require the lessees to equip all new and existing cranes installed on fixed platforms with anti-two block safety devices, but this new policy decision is not ''novel.'' The proposed rule simply addresses recognized gaps in our safety regulations. These minimum requirements are generally accepted practices that are included in API documents.

Regulatory Flexibility (RF) Act

The Department certifies that this rule will not have a significant economic effect on a substantial number of small entities as defined under the RF Act (5 U.S.C. 601 *et seq.*). An RF Analysis is not required. Accordingly, a Small Entity Compliance Guide is not required.

The provisions of this rule will not have a significant economic effect on lessees and operators, including those that are classified as small businesses. The Small Business Administration (SBA) defines a small business as having:

- Annual revenues of $5 million or less for exploration service and field service companies.
- Fewer than 500 employees for drilling companies and for companies that extract oil, gas, or natural gas liquids.

Offshore lessees/operators are classified under SBA's North American Industry Classification System (NAICS) code 211111 (Crude Petroleum and Natural Gas Extraction) and NAICS 213111 code (Drilling Oil and Gas Wells). We estimate approximately 130 companies will be affected by this rulemaking. According to SBA criteria, 39 companies are large firms, leaving up to 91 companies (70 percent) that may qualify as small firms with fewer than 500 employees.

We estimate that about 5 percent of the 4,000 cranes (200) located on the OCS need to be retrofitted with anti-two block safety devices. Retrofitting an existing crane with an anti-two block system would cost approximately $4,000. As 70 percent of the businesses operating on the OCS are small business firms, a corresponding 70 percent of the 200 cranes to be retrofitted would most likely impact small entities. The cost to small entities to retrofit these 140 cranes with anti-two block safety devices to comply with this standard is estimated to be $560,000 (140 x $4,000 = $560,000.) This does not constitute a significant impact upon a substantial number of small entities, and the safety benefits should far outweigh the cost of retrofitting. It should be noted that this would be a one-time cost during the initial period of implementation and will not be a recurring expense.

This proposed rule applies to all lessees and operating companies that operate cranes on OCS fixed platforms. Incorporation of this new document into MMS regulations will:

(1) Increase safety.

(2) Provide the oil and gas industry with uniform guidelines and detailed requirements for design and construction of pedestal-mounted cranes for OCS fixed platforms.

(3) Provide for consistency with other regulatory agencies such as the USCG.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions of MMS, call toll-free (888) 734–3247.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), SBREFA. This rule:

(a) Does not have an annual effect on the economy of $100 million or more. The proposed rule will not cause any significant costs to lessees or operators. The only costs will be the purchase of the API Spec 2C document, minor revisions to company operating procedures, and the installation of an anti-two block device on cranes installed on OCS fixed platforms that do not already have this safety device. These costs should be approximately $800,000 for the entire industry.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Will not have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This rule applies to lessees and contractors operating cranes on OCS fixed platforms.

Paperwork Reduction Act (PRA) of 1995

The proposed rule requires information collection, and an information collection request (form

OMB 83–I) has been submitted to OMB for review and approval under section 3507(d) of the PRA.

The title of the collection of information for this proposed rule is ''Proposed Rulemaking, 30 CFR 250, Subpart A—Crane Requirements.'' Potential respondents are approximately 130 Federal OCS lessees and operators. Responses to this collection of information are mandatory. The frequency of response is on occasion. This collection does not include proprietary information or questions of a sensitive nature.

Current regulations at § 250.108 include recordkeeping requirements for the testing, inspection, and maintenance of cranes installed on fixed platforms on the OCS. They also include recordkeeping requirements to document training of crane operators. The proposed rule expands the current recordkeeping requirements to include records on crane design, construction, and retrofitting. Records on training of rigger personnel, as well as crane operators, will also be required. The type of recordkeeping addressed in the proposed rule is most likely a usual and customary business practice, and the burden to make the records available for MMS review would be minimal. We estimate an additional 2 hours per respondent each year for the expanded recordkeeping requirements, for a total of 260 annual burden hours. MMS uses the information to determine that crane operations are safe and that crane operators and rigger personnel meet the physical qualifications and have completed appropriate training.

As part of our continuing effort to reduce paperwork and respondent burdens, MMS invites the public and other Federal agencies to comment on any aspect of the reporting burden in the proposed rule. You may submit your comments directly to the Office of Information and Regulatory Affairs, OMB. Send a copy of your comments to MMS. Refer to the **ADDRESSES** section for mailing instructions. MMS will summarize written comments and address them in the final rule preamble. The PRA provides that 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. OMB is required to make a decision concerning the collection of information contained in these proposed regulations between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it by August 20, 2001. This does not affect the deadline for the public to comment to MMS on the proposed regulations.

a. We specifically solicit comments on the following questions:

(1) Is the proposed collection of information necessary for MMS to properly perform its functions, and will it be useful?

(2) Are the estimates of the burden hours of the proposed collection reasonable?

(3) Do you have any suggestions that would enhance the quality, clarity, or usefulness of the information to be collected?

(4) Is there a way to minimize the information collection burden on those who are to respond, including the use of appropriate automated electronic, mechanical, or other forms of information technology?

b. In addition, the PRA requires agencies to estimate the total annual reporting and recordkeeping non-hour cost burden resulting from the collection of information. We have not identified any and solicit your comments on this item. For reporting and recordkeeping only, your response should split the cost estimate into two components: (1) The total capital and startup cost component, and (2) annual operation, maintenance, and purchase of services component. Your estimates should consider the costs to generate, maintain, and disclose or provide the information. You should describe the methods you use to estimate major cost factors, including system and technology acquisition, expected useful life of capital equipment, discount rate(s), and the period over which you incur costs. Capital and startup costs include, among other items, computers and software you purchase to prepare for collecting information; well control simulators, and testing equipment; and record storage facilities. Generally, your estimates should not include equipment or services purchased: before October 1, 1995; to comply with requirements not associated with the information collection; for reasons other than to provide information or keep records for the Government; or as part of customary and usual business or private practice.

Federalism (Executive Order 13132)

According to Executive Order 13132, this rule does not have Federalism implications. This rule does not substantially and directly affect the relationship between the Federal and State governments because it concerns the manufacturing requirements for specific equipment used in offshore oil and gas activities. The rule only affects manufacturers and users of such equipment. This rule does not impose costs on State or localities, as it only affects manufacturers and users of specific equipment used in offshore oil and gas activities.

Takings Implication Assessment (Executive Order 12630)

According to Executive Order 12630, this rule does not have significant Takings implications. A Takings Implication Assessment is not required.

Civil Justice Reform (Executive Order 12988)

According to Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act (NEPA) of 1969

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the NEPA is not required.

Unfunded Mandates Reform Act (UMRA) of 1995

This rule does not impose an unfunded mandate on State, local, and tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required.

Government-to-Government Relationship With Tribes

According to the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951) and 512 DM 2, we have determined that there are no effects from this action on federally recognized Indian tribes.

List of Subjects in 30 CFR Part 250

Continental shelf, Environmental impact statements, Environmental protection, Government contracts, Incorporation by reference, Investigations, Mineral royalties, Oil and gas development and production, Oil and gas exploration, Oil and gas reserves, Penalties, Pipelines, Public lands—mineral resources, Public lands—rights-of-way, Reporting and recordkeeping requirements, Sulphur development and production, Sulphur exploration, Surety bonds.

Dated: June 26, 2001.

Piet deWitt,

Acting Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Minerals Mangement Service proposes to amend 30 CFR Part 250 as follows:

PART 250—OIL AND GAS AND SULPHUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

1. The authority citation for part 250 continues to read as follows:

Authority: 43 U.S.C. 1331, *et seq.*

2. In § 250.108, the following changes are made:

A. Revise paragraph (a) as set forth below.

B. Redesignate paragraph (b) as paragraph (e).

C. Add new paragraphs (b), (c), (d), and (f) as set forth below.

§ 250.108 What requirements must I follow for cranes and other material-handling equipment?

(a) If you operate a crane installed on a fixed offshore platform, you must follow the American Petroleum Institute's Recommended Practice for Operation and Maintenance of Offshore Cranes (API RP 2D).

(b) If you install a new crane on a fixed offshore platform, the new crane must meet the requirements detailed in the American Petroleum Institute's Specification for Offshore Cranes (API Spec 2C).

(c) You must equip a crane, installed on a fixed offshore platform before [Date 30 days after the date of publication of the final rule], with an anti-two block safety device by [Date 1 Year and 30 days after the date of publication of the final rule].

(d) You must maintain records specific to a crane or the operation of a crane installed on a fixed offshore platform, as follows:

(1) Keep the qualification records of the crane operator and all rigger personnel at the fixed offshore platform for at least 4 years; and

(2) Keep all design, construction, inspection, maintenance, and testing records, including installation records for any anti-two block safety devices, for the life of the crane at the fixed offshore platform.

* * * * *

(f) For information on all standards mentioned in this section, see § 250.198.

3. In § 250.198, the following document incorporated by reference is added to the table in paragraph (e) in alphanumerical order.

§ 250.198 Documents incorporated by reference.

* * * * *

(e) * * *

Title of documents	Incorporated by reference at
* * *	* *
API Spec 2C, Specification for Offshore Cranes, Fifth Edition, April 1, 1995, API Stock No. G02C05	§ 250.108(a), (b).
* * *	* *

[FR Doc. 01–18022 Filed 7–18–01; 8:45 am]

BILLING CODE 4310–MR–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD7–01–056]

RIN 2115–AE47

Drawbridge Operation Regulations: Snake Creek Drawbridge, Islamorada, FL

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the operating regulations of the Snake Creek drawbridge (US 1) connecting Windley Key with Plantation Key at Islamorada, Florida. This rule would allow the drawbridge to open on signal except that from 7 a.m. until 6 p.m., the draw can open on the hour and half-hour. This action is intended to improve the movement of vehicular traffic while not unreasonably interfering with the movement of vessel traffic.

DATES: Comments and related material must reach the Coast Guard on or before September 17, 2001.

ADDRESSES: You may mail comments and related material to Commander (obr), Seventh Coast Guard District, 909 S.E. 1st Avenue, Room 406, Miami, FL 33131. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD07–01–056] and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 S.E. 1st Avenue, Room 406, Miami, FL 33131 between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Bridge Branch, 909 SE 1st Ave, Miami, FL 33130, telephone number 305–415–6743.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [CGD07–01–056], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Bridge Branch, Seventh Coast Guard District, 909 SE 1st Ave, Room 406, Miami, FL 33131, explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Snake Creek bascule bridge is a two lane narrow undivided arterial roadway, which is the only roadway into and out of the Florida Keys and is already severely congested due to insufficient capacity. Existing operating schedule is on demand and can be found at 33 CFR 117.5. The proposed rule will allow the bridge owner to open the bridge on the hour and half hour during the heavy vehicle traffic period from 7 a.m. until 6 p.m.

Discussion of Proposed Rule

The proposed rule allows the bridge to open on signal except that from 7 a.m. until 6 p.m. the bridge can open on the hour and half-hour. This should aid in the movement of traffic across the bridge, while not unreasonably interfering with the movement of vessel traffic through the draw.

Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not

reviewed it under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, l979).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

This proposed rule would affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit under the Snake Creek bridge during the hours of 7 a.m. to 6 p.m. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities because the number of openings that occur during the proposed period of additional regulations is less than twice per hour and the maximum waiting time will be 30 minutes.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

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

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this proposed rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This proposed rule would not impose an unfunded mandate.

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Environment

We considered the environmental impact of this proposed rule and concluded that, under figure 2–1, paragraph (32)(e) of Commandant Instruction M16475.lC, this proposed rule is categorically excluded from further environmental documentation.

Indian Tribal Governments

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

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Section 117.331 is added to read as follows:

§ 117.331 Snake Creek.

The draw of the Snake Creek bridge at Islamorada, shall open on signal, except that from 7 a.m. to 6 p.m. the draw need open only on the hour and the half-hour. Public vessels of the United States and vessels in distress shall be passed through the draw as soon as possible.

Dated: July 2, 2001.

James S. Carmichael,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 01–17995 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[WH–FRL–7015–4]

RIN 2040–AB75

National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: Today's action proposes and requests comment on a range of MCL options for the drinking water standard for arsenic. In particular, EPA is requesting comment on whether the data and technical analyses associated with the arsenic rule published in the January 22, 2001, **Federal Register** (66 FR 6976) as well as any new information that may be available would support setting the enforceable arsenic standard, or Maximum Contaminant Level (MCL), at 3 micrograms per liter (μg/L) (the feasible level), 5 μg/L (the level proposed in June 2000), 10 μg/L (the level published in the January 2001 rule), or 20 μg/L.

To assist commenters, today's document provides a brief summary of the principal data and technical analyses that accompanied the January 2001 arsenic rule and solicits comment on key issues associated with this information and analyses. In providing comment on these issues, commenters should focus on the preamble, technical support documents, and record associated with the January 2001 rule (not the June 2000 proposal (65 FR 38888)) because EPA made many changes to the analyses supporting the January decisions in response to public comment on the June 2000 proposal. In developing comments, commenters may also wish to consider information EPA plans to have in a notice in the fall of 2001, which will request comment on the results of the additional analyses of key scientific, technical and economic elements of the rule. The comment period for today's notice ends October 31, 2001, because the Agency expects this comment period to overlap with the fall 2001 notice's comment period on the scientific, cost, and benefits reviews.

On May 22, 2001, EPA published in the **Federal Register** (66 FR 6976) a final rule delaying the effective date of the arsenic rule until February 22, 2002, in order to conduct reviews of the science and costing analyses. Additional information about these reviews as well as a review of the benefits analysis for the January 22, 2001, rule are provided in today's document. EPA expects the results of these reviews to be available within the comment period for today's proposal.

This proposal does not affect the clarifications to compliance and new source contaminants monitoring regulations also issued on January 22, 2001, (66 FR 6976), for inorganic, volatile organic, and synthetic organic contaminants. Those regulations go into effect on January 22, 2004, as provided in the January 22, 2001, final rule.

DATES: Your comments on a range of arsenic MCLs from 3 μg/L to 20 μg/L must be in writing and either postmarked or received by EPA's Water Docket by October 31, 2001.

ADDRESSES: You may mail your written comments to the W–99–16–VI Arsenic Comments Clerk, Water Docket (MC–4101); U.S. EPA; 1200 Pennsylvania Avenue, NW.; Washington, DC 20460. Comments may be hand delivered (*e.g.,* courier or overnight delivery service) to EPA's Water Docket, located at 401 M Street, SW.; East Tower Basement Room 57; in Washington, DC; between 9 a.m. and 3:30 p.m. Eastern Time, Monday through Friday. Comments may be submitted electronically to *ow-docket@epa.gov.* See **SUPPLEMENTARY INFORMATION** for file formats and other information about electronic filing and docket review.

FOR FURTHER INFORMATION CONTACT: The Safe Drinking Water Hotline, phone: (800) 426–4791 or (703) 285–1093, e-mail: *hotline-sdwa@epa.gov* for general information, meeting information, and copies of arsenic regulations and support documents. For inquiries about the on-going cost of compliance review, contact: Mr. Amit Kapadia, (202) 260–1688, e-mail: *kapadia.amit@epa.gov.* For all other questions about this document, contact Irene Dooley, (202) 260–9531, e-mail: *dooley.irene@epa.gov.*

SUPPLEMENTARY INFORMATION:

Regulated Entities

A public water system (PWS), as defined in 40 CFR 141.2, provides water to the public for human consumption through pipes or other constructed conveyances, if such system has ''at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year.'' A public water system is either a community water system (CWS) or a non-community water system (NCWS). A community water system, as defined in § 141.2, is ''a public water system which serves at least fifteen service connections used by year-round residents or regularly serves at least twenty-five year-round residents.'' The definition in § 141.2 for a non-transient non-community water system (NTNCWS) is ''a public water system that is not a [CWS] and that regularly serves at least 25 of the same persons over 6 months per year.'' EPA has an inventory totaling over 54,000 CWSs and approximately 20,000 NTNCWSs nationwide. Entities potentially regulated by this action are CWSs and NTNCWSs. The following table provides examples of the regulated entities under this rule.

TABLE OF REGULATED ENTITIES

Category	Examples of potentially regulated entities
Industry	Privately owned/operated community water supply systems using ground water, surface water, or mixed ground water and surface water.
State, State, Tribal, and Local Government.	State, Tribal, or local government-owned/operated water supply systems using ground water, surface water, or mixed ground water and surface water.
Federal Government.	Federally owned/operated community water supply systems using ground water, surface water, or mixed ground water and surface water.

The table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in §§ 141.11 and 141.62 as revised by the January 22, 2001 (66 FR 6976) arsenic rule.

Additional Information for Commenters

No facsimiles (faxes), compressed or zipped files will be accepted, and comments must be submitted in writing. In providing comment on these issues, commenters should focus on the preamble, technical support documents, and record associated with the January 2001 arsenic in drinking water regulation (not the June 2000 proposal (65 FR 38888)). EPA addressed comments prepared for the June 2000 proposed rule in the response-to-comments document in the docket for W–99–16–III and summarized responses

to the major comments in the preamble of the January 2001 regulation. Please submit an original and three copies of your comments and enclosures (including references) and identify your submission by the docket number W–99–16–VI. To ensure that EPA can read, understand, and therefore properly respond to comments, the Agency would prefer that comments cite, where possible, the question(s) or sections and page numbers in the document or supporting documents to which each comment refers. Commenters should use a separate paragraph for each issue discussed. Commenters who want EPA to acknowledge receipt of their comments should include a self-addressed, stamped envelope.

EPA uses WordPerfect as its standard software, so electronic submissions (including 3.5 inch floppy disks) must be submitted in WordPerfect 8 (or older version) or ASCII file format (unless four hard copies are also submitted). Comments submitted in other electronic formats (*e.g.,* Word, pdf, Excel, and compressed or zipped files) must also be submitted as hard copies. For purposes of dating dual hard copy/electronic copy submissions, the date of the electronic copy will be recorded as the date submitted. Please indicate that you are sending hard copies so the Docket can link your two submissions rather than log in two sets of your comments. Electronic comments on this document may be filed online at many Federal Depository Libraries.

The Agency's response-to-comments document for W–99–16–VI will address the comments received for this proposal, and this document will be made available in the docket. Since the comment period ends October 31, 2001, the response-to-comment document will not be completed until sometime later in the fall of 2001. To facilitate development of a response-to-comments document, EPA appreciates receiving an electronic version in addition to the original and three copies for large submissions (*e.g.,* over 10 pages). The Agency does not send out individual replies to respond to those who submit comments.

Availability of Docket

For an appointment to review the docket for this rulemaking, call (202) 260–3027 between 9 a.m. and 3:30 p.m. Eastern Time, Monday through Friday and refer to Docket W–99–16–VI. Every user is entitled to 100 free pages, and after that the Docket charges 15 cents a page. Users are invoiced after they copy $25, which is 267 photocopied pages. The Safe Drinking Water Hotline can provide some hard copies of some of the supporting documentation and some electronically, phone: (800) 426–4791 or (703) 285–1093, e-mail: *hotline-sdwa@epa.gov.* EPA's arsenic-in-drinking-water web page contains links to the arsenic **Federal Register** notices and other supporting material at *www.epa.gov/safewater/arsenic.html.*

Abbreviations Used in This Proposed Rule

>—greater than
<—less than
§—section
μg—micrograms, one millionth of a gram (3.5×10^{-8} ounce, 0.000000035 oz.)
μg/L—micrograms per liter, same as parts per billion (ppb)
AES—Atomic emission spectroscopy
ARBRP—Arsenic Rule Benefits Review Panel of SAB
AWWARF—American Water Works Association Research Foundation
BAT—Best available technology
CCR—Consumer Confidence Report
CFR—Code of Federal Regulations
CWS—Community water system
DWSRF—Drinking Water State Revolving Fund
EA—Economic analysis
EO—Executive Order
EPA—U.S. Environmental Protection Agency
ERDDAA—Environmental Research, Development, and Demonstration Authorization Act, SAB
FACA—Federal Advisory Committee Act
FR—**Federal Register**
FRFA—Final regulatory flexibility analysis
FSIS—Federalism summary impact statement
GW—Ground water
ICP—Inductively coupled plasma
ICR—Information Collection Request
ISCV—Intra-system coefficient of variation
IRFA—Initial regulatory flexibility analysis
ISCV—Intra-system coefficients of variation
L—Liter, also referred to as lower case ''l'' in older citations
MCL—Maximum contaminant level
MCLG—Maximum contaminant level goal
mg—milligrams, one thousandth of a gram, 1 mg = 1,000 μg
mg/L—milligrams per liter
NAS—National Academy of Sciences
NCWS—Non-community water system
NDWAC—National Drinking Water Advisory Council, EPA FACA group
NODA—Notice of Data Availability
NPDWR—National primary drinking water regulation
NRC—National Research Council, the operating arm of NAS
NTNCWS—Non-transient non-community water system
NTTAA—National Technology Transfer and Advancement Act
OMB—Office of Management and Budget
P.L.—Public Law
PNR—Public Notification Rule
POTW—Publicly owned treatment works, wastewater treatment
POU—Point-of-use treatment devices
PRA—Paperwork Reduction Act
PWS—Public water systems
REF—Relative exposure factors
RFA—Regulatory Flexibility Act
RUS—Rural Utilities Service
SAB—Science Advisory Board
SBA—Small Business Administration
SBAR—Small Business Advocacy Review
SBREFA—Small Business Regulatory Enforcement Fairness Act
SDWA—Safe Drinking Water Act
SW—Surface water
UMRA—Unfunded Mandates Reform Act
U.S.—United States
USGS—U.S. Geological Survey
VSL—Value of statistical life
WTP—Willingness to pay

Table of Contents

I. Background and History Preceding This Document
A. What is in the arsenic rule published on January 22, 2001?
1. Summary of arsenic regulation
2. Changes to the Consumer Confidence Report (CCR) for arsenic
3. Changes to public notification for arsenic
4. Arsenic rule's effect on State/Tribal primacy programs
B. What did EPA's Administrator announce on March 20, 2001?
C. How has the effective date of the arsenic rule changed?
1. March 23, 2001 **Federal Register** 60-day delay notice
2. April 23, 2001 **Federal Register** 9-month extension proposal
3. May 22, 2001 **Federal Register** February 22, 2002 effective date
4. Effect on CCR for calendar year 2001
D. With what regulatory standard for arsenic must systems comply now?
II. EPA's Plans to Review Parts of the Arsenic Rule
A. What is the purpose of today's action and what happens now?
B. What approach will EPA use to review the science, costs, and benefits of the rule?
1. Overview
2. Approach to review of health science
3. Approach to review of cost of compliance estimates
4. Approach to review of benefits estimates
C. How did EPA assess the occurrence of arsenic?
1. Summary of arsenic occurrence analysis
2. Request for occurrence comments
D. How did EPA evaluate the health risks of arsenic in drinking water?
1. Summary of health risk elements
2. Request for comment on health issues
E. How did EPA calculate the national costs of compliance with the arsenic in drinking water rule?
1. Summary of cost elements of January 22, 2001 rule and record
2. List of cost issues and request for comments
F. How did EPA calculate the benefits of the arsenic rule?
1. Summary of the January 22, 2001, benefits assessment
2. List of key benefit analysis issues
a. Discounting benefits over a cancer latency period
b. Consideration of non-quantifiable benefits in the regulatory decision-making process
3. Request for comments on benefits

G. What process is EPA planning for review of financial, technical, and planning tools for small systems?
1. Small system review process
2. List of small system issues
a. Affordability, availability of financial assistance, and treatment technology
b. SDWA Capacity Development Framework
3. Request for small systems comment
III. Process to be Employed after Technical Reviews and Public Comment
A. How will EPA notify the public of results of the technical reviews and the nature of the public comments?
B. What process will EPA use to make final decisions on the rule?
IV. Administrative Requirements
A. Executive Order 12866, Regulatory Planning and Review
B. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.
C. Unfunded Mandates Reform Act (UMRA) of 1995
D. Paperwork Reduction Act (PRA)
E. National Technology Transfer and Advancement Act
F. Executive Order 12898: Environmental Justice
G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
H. Executive Order 13132, Federalism
I. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments
J. Consultations with the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services
K. Likely Effect of Compliance With the Arsenic Rule on the Technical, Financial, and Managerial Capacity of Public Water Systems
L. Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
V. References

I. Background and History Preceding This Document

A. What Is in the Arsenic Rule Published on January 22, 2001?

1. Summary of Arsenic Regulation

In the Monday, January 22, 2001, **Federal Register** (EPA 2001a), EPA issued regulations revising the arsenic drinking water standard and clarifying compliance and new-source contaminants monitoring provisions (66 FR 6976). The Agency established a health-based, non-enforceable Maximum Contaminant Level Goal (MCLG) for arsenic of zero milligrams per liter (mg/L) in § 141.15(b) and an enforceable Maximum Contaminant Level (MCL) for arsenic of 0.01 mg/L (*i.e.,* 10 micrograms per liter (μg/L)) for both community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) in § 141.62(b)(16). (Although EPA lists drinking water standards in Title 40 of the Code of Federal Regulations (40 CFR) in units of mg/L, except where noted, the Agency will refer to arsenic concentrations in μg/L in this preamble.) As part of the arsenic regulation, EPA also listed the approved analytical methods to measure compliance (§ 141.23(k)(1)), as well as the best available technologies (BAT) (§ 141.62(b)), small system technologies that could achieve compliance with the MCL (§ 141.62(d)), consumer confidence report requirements for CWSs, and public notification requirements for PWSs for the new MCL. Because the Agency identified affordable technologies for small systems, the rule did not list any small system variance technologies under § 1412(b)(15)(A) of the Safe Drinking Water Act (SDWA).

All but one of the five existing arsenic analytical technologies can be used for compliance determinations. As noted in the June 2000 proposal (65 FR 38888 at 38913) and January 2001 rule (66 FR 6976 at 6988), inductively coupled plasma (ICP)—atomic emission spectroscopy (AES) methods in EPA Method 200.7 and Standard Methods 3120 B have unacceptably high detection limits (see footnote 15 to table in § 141.23(k)(1); 66 FR 6976 at 7062).

EPA established an effective date of March 23, 2001, and a compliance date (§ 141.6(j)) for the arsenic regulation of January 23, 2006, five years after issuance for all systems. However, the consumer confidence reporting requirements for arsenic listed in § 141.6(j) had a March 23, 2001 compliance date.

EPA intended to issue a small entity implementation or compliance guide shortly after issuing the rule (66 FR 6976 at 7033). However, because of the on-going reviews, the Agency believes that it is premature to distribute small entity guidance at this time.

2. Changes to the Consumer Confidence Report (CCR) for Arsenic

On August 19, 1998, EPA issued part 141 subpart O, the final rule requiring community water systems to provide annual water quality report to their customers (63 FR 44512; EPA, 1998a). Reports are now due by July 1 for the preceding calendar year (§ 141.152(a)). Any time arsenic is detected, the report must list the MCL (50 μg/L), the MCLG (none), and the highest level used to determine compliance and the range of detected levels, according to §§ 141.153(d)(4)(i), (ii), and (iv), respectively. Section 141.153(d)(6) requires the CCR to identify MCL violations, steps taken to address violations, and potential health effects using the language in appendix A of subpart O. In addition, using the authority of section 1414(c)(4)(B)(vi) of SDWA (63 FR 44512 at 44514), systems that detect arsenic between 25 μg/L and 50 μg/L are also required to provide an informational statement (§ 141.154(b)).

As published, the arsenic rule would make two reporting changes for systems detecting arsenic below 50 μg/L that would affect the CCR due by July 1, 2002, for calendar year 2001 (66 FR 6976 at 6991). First, CWSs would be required to include a revised informational statement (§ 141.154(b)) about arsenic when detected from 5 μg/L to 10 μg/L. In the arsenic rule, the Agency retained § 141.154(b) reporting requirements because the MCL is higher than the technologically feasible MCL (66 FR 6976 at 6991). Second, as proposed in § 141.154(b) and finalized in § 141.154(f), systems detecting from 10 μg/L to 50 μg/L would also provide the arsenic health language in appendix A to subpart O (§ 141.154(f)), even though systems are in compliance with the 50 μg/L MCL through January 22, 2006. (January 23, 2006, is the effective date for the MCL of 10 μg/L (§ 141.60(b)(4)).) As explained in section I.C.4, the current 9-month extension of the effective date until February 22, 2002, affects the CCR requirements of the January 2001 rule for calendar year 2001 reports.

3. Changes to Public Notification for Arsenic

On May 4, 2000, EPA issued the final Public Notification Rule (PNR) to revise the minimum requirements that public water systems must meet for public notification of violations of EPA's drinking water standards (65 FR 25982; EPA, 2000b). Systems must begin to comply with the revised PNR regulations on October 31, 2000 (if they are in jurisdictions where the program is directly implemented by EPA, such as Wyoming and many Tribes), or on the date that a primacy State/Tribe adopts the new requirements (no later than May 6, 2002).

The January 2001 arsenic rule would require CWSs and NTNCWSs to provide a Tier 2 public notice for arsenic MCL violations (> 10 μg/L) and to provide a Tier 3 public notice for violations of the monitoring and testing procedure requirements. In addition, public water systems must give notice for all violations when operating under a variance or exemption and for violating conditions of the variance or exemption. The arsenic regulation (66 FR 6976) amended the PNR, subpart Q of part

141, for purposes of compliance starting January 23, 2006 (§ 141.6(j); 66 FR 6976 at 7061).

4. Arsenic Rule's Effect on State/Tribal Primacy Programs

States must submit applications for revised primacy no later than 2 years after promulgation of a new standard unless the State requests and is granted an additional 2-year extension. Interim primacy enforcement authority (§ 142.12(e)) allows States to implement and enforce drinking water regulations once State regulations are effective and the State has submitted a complete and final primacy revision application.

In the arsenic rule, EPA reduced requirements for submitting revisions for existing regulated contaminants (§§ 142.16(e) and (j)), so that information required in § 142.16(e) is not required for States revising the MCL for arsenic. In addition, revisions to § 142.16(j) clarified that States may inform the Agency in their applications of any changes to their existing monitoring plans and waiver procedures. These regulations are effective for purpose of compliance on January 22, 2004 (§ 141.6(k); 66 FR 6976 at 7061).

Currently, the Navajo Nation is the only federally recognized Indian Tribe with primacy to enforce drinking water regulations. EPA Regions implement the rules for all other Tribes under section 1451(a)(1) of SDWA. Tribes must submit a primacy application (§ 142.76) to have oversight for the inorganic contaminants (*i.e.,* the Phase II/V rule) to obtain the authority for the revised arsenic MCL. Tribes with primacy for drinking water programs are eligible for grants and contract assistance (section1451(a)(3) of SDWA). Tribes are also eligible for grants under the Drinking Water State Revolving Fund Tribal set-aside grant program authorized by section 1452(i) of SDWA for public water system expenditures.

EPA is aware of the practical implications of the ongoing reviews and delayed effective date on States and Tribes in terms of primacy and other requirements. EPA will consult with States and interested Tribes before addressing the effects on State primacy in future **Federal Register** notices.

B. What Did EPA's Administrator Announce on March 20, 2001?

On March 20, 2001, the Administrator announced in a press release that EPA would delay the effective date for the arsenic rule 60 days. That extension was in accordance with the White House (WH) memorandum of January 20, 2001, entitled ''Regulatory Review Plan,'' which was published in the **Federal Register** (WH 2001) on January 24, 2001 (66 FR 7702). The January 20, 2001, memorandum from Andrew Card, Assistant to the President and Chief of Staff, communicated the President's plan to ensure that his appointees had the opportunity to review new regulations ''at the outset of his Administration'' in order to avoid ''costly, burdensome, or unnecessary regulation * * *.'' For regulations that had been published in the **Federal Register**, but were not yet in effect, the memorandum requested departments and agencies to postpone their effective dates for 60 days. In order to provide safe and affordable drinking water, the Administrator announced plans to seek independent reviews of the science behind the arsenic standard and the cost estimates used to develop the rule.

C. How Has the Effective Date of the Arsenic Rule Changed?

1. March 23, 2001 **Federal Register** 60-Day Delay Notice

On March 23, 2001 (EPA 2001b), the **Federal Register** published EPA's 60-day delay of the effective date for the arsenic regulation (66 FR 16134), in accordance with the White House memorandum, ''Regulatory Review Plan'' (66 FR 7702). The delay changed the effective date for the arsenic regulation from March 23, 2001, to May 22, 2001, including the dates for compliance with the consumer confidence reporting requirements for § 141.154(b) and (f) that were specifically linked to the new arsenic regulation.

2. April 23, 2001 **Federal Register** 9-Month Extension Proposal

On April 23, 2001 (EPA 2001c), EPA proposed (66 FR 20580) to extend the effective date for the arsenic rule from May 22, 2001, to February 22, 2002, in order to obtain independent reviews of the science, cost, and benefit analyses used to support the arsenic in drinking water regulation. The notice outlined the process for the science and cost reviews.

3. May 22, 2001 **Federal Register** February 22, 2002 Effective Date

After reviewing the comments received on the 9-month proposed delay of the effective date, the Agency issued a final rule (EPA 2001f) on May 22, 2001 (66 FR 28342), delaying the final effective date until February 22, 2001, so the Agency could proceed as planned with the proposed reviews and opportunities for additional public comment. EPA identified mechanisms for reviewing the science and cost estimates in the notice and provided responses to comments in the preamble (66 FR 28342 at 28345) that are in the response-to-comment document for docket W–99–16–IV (EPA 2001).

4. Effect on CCR for Calendar Year 2001

The final rule for the 9-month delay (66 FR 28342 at 28350) also changed the § 141.6(j) compliance date to February 22, 2002, for the new arsenic consumer confidence reporting requirements in §§ 141.165(b) and (f). The delay will affect some systems that send out calendar year 2001 reports. CWSs that send out calendar year 2001 reports prior to February 22, 2002 must comply with the old arsenic CCR requirements (those in effect prior to the January 2001 rule). CWSs that send their reports after February 22, 2002, will have to comply with the new arsenic CCR requirements. In light of the current analyses being conducted on aspects of the arsenic rule, the Agency plans to address CCR reporting issues and options in the fall 2001 notice.

D. With What Regulatory Standard for Arsenic Must Systems Comply Now?

In the process of extending the effective date for the arsenic rule, EPA has not changed the compliance date for the MCL issued in the January 2001 rule. Until January 23, 2006, the MCL for arsenic is 50 μg/L, which only applies to CWSs (§§ 141.11(a) and (b)), and there is no MCLG for arsenic (§ 141.51(b)).

II. EPA's Plans to Review Parts of the Arsenic Rule

A. What Is the Purpose of Today's Action and What Happens Now?

The January 22, 2001, rule established an MCLG of 0 μg/L and an MCL of 10 μg/L for arsenic and explained in detail the rationale for this decision. However, because of concerns raised by some stakeholders concerning the arsenic in drinking water regulation, especially small community systems that may bear a high cost burden to comply with the new standard, EPA has decided to request further comment on the arsenic standard set in the January 22, 2001, drinking water rule.

As a result, today EPA proposes and requests stakeholder input on a range of MCL options for arsenic from 3 μg/L to 20 μg/L. In developing comments, commenters should refer to the information provided in the January 22, 2001, arsenic rule, the background documents supporting that rule, the notice and request for comment on the scientific, technical, and benefits

reviews that EPA plans to publish in the fall of 2001, and any new (post-January 2001) information commenters wish to provide. EPA is accepting comments until October 31, 2001, on today's notice to facilitate commenters' ability to examine the most current information. The Agency also anticipates that the comment period for the notice summarizing the fall 2001 reviews will overlap with today's comment period, thereby allowing commenters to provide a single set of comments covering both today's notice and the expected fall 2001 notice, if they wish.

EPA is also undertaking additional analyses on science, cost, and benefits issues, as explained in section II.B., and expects these analyses to be completed in August 2001. Once the analyses are completed, EPA will consider this new information and provide for an additional opportunity for public comment on the new analyses along with EPA's preliminary conclusion about whether the January 2001 arsenic rule should be revised, and if so, what the revised standard should be. EPA will consider the public comments, as well as the record for the arsenic rule for this reconsideration, and issue a final decision on whether to revise the January 2001 rule. In particular, EPA is considering whether to retain the revised MCL of 10 μg/L or replace it with another standard—specifically, 3 μg/L (the feasible level), 5 μg/L (the level proposed in June 2000) or 20 μg/L (another alternative considered in the June 2000 proposal). If EPA does decide to revise the January 2001 rule, EPA will issue a new revised rule.

B. What Approach Will EPA Use To Review the Science, Costs, and Benefits of the Rule?

1. Overview

EPA understands and appreciates that the question of setting a final arsenic in drinking water standard is a controversial one for several reasons. From an economic standpoint, the new regulation can be expected to have significant impacts on a number of drinking water utilities, especially those serving less than 10,000 people in areas of high naturally occurring arsenic. Stakeholders have an understandable desire to ensure that any new regulation be based on accurate and reliable compliance cost estimates. Stakeholders also want to be confident that the health risks associated with a new standard have been appropriately evaluated and are based on the best available science.

The Agency is committed to safe and affordable drinking water for all Americans. At the same time, we want to be sure that the conclusions about arsenic in the rule are supported by the best available science and policy decisions based on thorough cost-benefit considerations. The Agency is therefore moving rapidly to review arsenic research and national cost and benefit estimates related to the arsenic standard so that communities that need to reduce arsenic in drinking water can proceed with confidence that the new standard is based on sound science and accurate cost-benefit estimates. Independent review of the science, cost, and benefits analysis behind the arsenic in drinking water standard will help resolve questions that have arisen about the health basis and costs and benefits of reducing arsenic in drinking water.

EPA's criteria for conducting the reviews will be to ensure that reviewers are recognized experts in their fields and are as impartial and objective as possible; that the reviews can be completed in August 2001; and that the results of the reviews are made available for public comment. EPA plans to utilize the mechanisms for the reviews described in the following section.

EPA does not plan to seek outside, expert review of its approaches for estimating occurrence or determining the availability of analytical methods and their capabilities but is requesting further public comment on these aspects of the January 2001 rule.

2. Approach to Review of Health Science

Under a cooperative agreement with EPA, on May 21 the National Academy of Sciences (NAS) convened a subcommittee of the National Research Council's (NRC) Committee on Toxicology to prepare a report updating the scientific analyses, uncertainties, findings and recommendations of the report ''Arsenic in Drinking Water (NRC 1999).'' NAS posts information about the arsenic study, including project scope, the subcommittee membership and biographies, meetings, and meeting summaries of the closed sessions (NRC 2001a and NRC 2001b) in the website *www.nationalacademies.org* under Current Projects (the short cut to the direct NRC arsenic project address, *www4.nas.edu/cp.nsf/af89ea56d4264b948525639b0043e7c7/7ae42f9d0397214b85256a3100711f15?OpenDocument,* is available from *www.epa.gov/safewater/ arsenic.html*). Information on NRC's committee process is also available on the NAS website under Frequently Asked Questions at *www.nationalacademies.org/ about/ faq4.html.* Specifically, the subcommittee is reviewing relevant toxicological and health-effects studies published and data developed since the 1999 NRC report, including the toxicological risk-related analyses performed by EPA in support of its regulatory decision-making for arsenic in drinking water and the health effects discussion in EPA's SAB December 2000 report entitled, ''Arsenic Proposed Drinking Water Regulation: A Science Advisory Board Review of Certain Elements of the Proposal (EPA 2000f).'' The subcommittee is addressing only scientific topics relevant to toxicological risk and health effects of arsenic.

The subcommittee will meet approximately three times to discuss and evaluate issues and will produce a consensus report in August 2001. On May 21, the NRC subcommittee heard presentations from EPA, the Small Business Administration, a consultant for Albuquerque, researchers, industry, environmental and other interested or affected parties. At the open session meeting on June 20, the committee heard from EPA's Administrator. The draft consensus report will undergo the established NRC peer review process before NRC issues the final report that is available to the public. In addition, EPA will make the NRC's report available to the general public and request comment on its recommendations as part of a notice this fall.

3. Approach To Review of Cost of Compliance Estimates

The National Drinking Water Advisory Council (NDWAC) is chartered under the Federal Advisory Committee Act (FACA) to advise, consult with, and make recommendations to EPA. The Agency asked the NDWAC, and the Council agreed to convene a panel of nationally recognized technical experts to review the cost of compliance estimates associated with the regulatory options that were considered in the proposed rule and discussed in the January 2001 rule. On May 4, 2001 (EPA 2001d), EPA requested nominations for the working group (66 FR 22551). In particular, the working group is reviewing the costing methodologies, assumptions, and information underlying the system-size as well as the aggregated national estimate of system costs underlying the January 2001 arsenic in drinking water rule. As a part of this review, the group is evaluating significant alternative costing approaches or critiques where there is adequate information upon which to evaluate the basis for such alternate estimates or approaches.

The working group first met May 29–30, 2001, as announced in the May 22,

2001, **Federal Register** (EPA 2001f). Working group members have been asked to attend a series of meetings (June 28–29 in Denver, Colorado; July 9–10 in Phoenix, Arizona; and July 19–20 in Washington, DC) over the summer of 2001 (June 15, 2001 **Federal Register**, EPA 2001h), participate in discussion of key issues and assumptions at these meetings, and review work products of the working group. The working group will make a recommendation to the full NDWAC based on its review of the national cost estimates. The NDWAC, will in turn, make a recommendation to EPA. All NDWAC working group meetings and full NDWAC meetings are open to the public, and meeting information is posted on the calendar accessible from *www.epa.gov/safewater.* EPA posts the working group member list and meeting summaries at *http://www.epa.gov/safewater/ndwac/council.html.* The report of the working group and the final recommendations of the NDWAC will be made available for public review and comment.

4. Approach To Review of Benefits Estimates

The EPA Science Advisory Board (SAB), which also is chartered under the FACA, was established in 1978 by the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA) (42 U.S.C. 4365), to provide such scientific advice as may be requested by the Administrator. At the request of the Agency the SAB has convened a panel, the Arsenic Rule Benefits Review Panel (ARBRP), to review the Agency's analysis of quantified and unquantified benefits associated with the arsenic drinking water rule. The Agency has asked this panel of nationally recognized technical experts to review the Agency's analysis of quantified and unquantified arsenic benefits analysis as required by SDWA, and evaluate whether the components, methodology, criteria and estimates reflected in EPA's benefits analysis are reasonable and appropriate in light of: (1) The SAB's benefits transfer report (EPA 2000d; available on the SAB Website at *www.epa.gov/sab/eeacf013.pdf*); (2) EPA's Guidelines for Preparing Economic Analyses (EPA 20001; *www.epa.gov/economics*); (3) relevant requirements of the Safe Drinking Water Act (SDWA; *www.epa.gov/safewater/sdwa/sdwa.html*); (4) NDWAC recommendations to EPA on benefits (unpublished October 29, 1998, Benefits Working Group Report to the National Drinking Water Advisory Council; EPA 1998b); and (5) recent literature.

Panel members have been asked to attend one or more meetings over the summer of 2001, participate in discussion of key issues and assumptions at these meetings, and review the previously described documents and literature. The first meeting of the ARBRP will be on July 19–20, in Washington, D.C. (EPA 2001i). To ensure that the SAB's recommendations are fully considered in decision making, the Agency has asked for a report to be made available to the Administrator in August 2001 to coincide with the findings and recommendations from independent reviews of the health effects by NRC and costs by NDWAC. All ARBRP meetings are open to the public and time will be allotted for presentations by the public. Meeting information is posted on the calendar accessible from *www.epa.gov/safewater.* The report of the ARBRP and the final recommendations of the SAB will be made available for public review and comment.

C. How Did EPA Assess the Occurrence of Arsenic?

1. Summary of Arsenic Occurrence Analysis

EPA's occurrence estimates were a fundamental building block in cost of compliance estimates as well as its benefits estimates. To develop this occurrence estimate, EPA used arsenic compliance monitoring data consisting of almost 77,000 observations from 25 States to estimate the distribution of arsenic in finished drinking water in public water systems (PWS) in the U.S. These States voluntarily submitted the data from public water systems. Figure V–1 in the June 2000 proposed rule (65 FR 38888 at 38906) is a map of the 25 States from which EPA used data to estimate occurrence. These States are distributed throughout the U.S., with at least one located in each of the seven geographic regions that the Agency used in its analysis (EPA 2000h). Ten other States (Florida, Idaho, Iowa, Louisiana, Pennsylvania, South Dakota, Maryland, Nebraska, Vermont, and West Virginia) submitted compliance monitoring data, but those data were not complete enough to estimate State occurrence (66 FR 6976 at 7029). EPA lists the database parameters used to derive its national occurrence estimate in Appendix D–2 of the occurrence document (EPA 2000h).

In order to estimate a national occurrence distribution of arsenic, EPA began with individual water systems and built up estimates for States, regions, and the nation. For each PWS in its database, the Agency estimated the mean arsenic concentration over time in finished water. (Although MCL compliance is determined by computing a running annual average of quarterly samples, EPA elected to characterize arsenic occurrence in each system in terms of the mean arsenic concentration over time, rather than by a set of running averages; for the benefits estimates, the long-term mean is preferable, because health risks are determined by mean exposure to arsenic over time; for the cost estimates, the approach used may not accurately predict costs in all cases, since some systems with a long-term average below the standard might still exceed it during some compliance cycles.) Next, the Agency collected the system mean estimates into State distributions, then merged the State distributions into regional and finally, national distributions. The regions used in the analysis are shown in Figure V–1 in the June 2000 proposed rule (65 FR 38888 at 38906). In combining the regional distributions into a national distribution, the Agency weighted each region by the total number of systems in the region, not just the number of systems in the States in its database. This procedure has the same effect as assigning the regional distributions to the 25 States for which there are no observations in the database.

EPA estimated separate arsenic occurrence distributions for community water systems (CWS) and non-transient, non-community water systems (NTNCWS), and for systems with ground water (GW) and surface water (SW) sources. Systems identified as having ground water under the influence of surface water were treated as surface water systems. Table III.C–1 (66 FR 6976 at 6996) shows the Agency had data from 17 States for ground water NTNCWS, compared to 25 States for CWS, so there are, on average, fewer States with NTNCWS data in each region. Moreover there is no data about NTNCWS from any States in the Southeast region (Alabama, Florida, Georgia, Mississippi, and Tennessee). EPA therefore used the occurrence distribution for ground water CWS as a surrogate for ground water NTNCWS in the Southeast. For surface water NTNCWS, EPA used the occurrence estimates from surface water CWS, because the characteristics of source water for NTNCWS are expected to be similar to source water for CWS, and there is a larger CWS data set to draw from.

Table III.C–5 of the January 2001 rule (66 FR 6976 at 6998) shows EPA's estimated arsenic occurrence distributions for the U.S. The results are comparable to those of two other arsenic

occurrence studies: the National Arsenic Occurrence Survey (Frey and Edwards, 1997) and USGS (2000).

In addition to the distributions of system means, EPA estimated nationwide intra-system coefficients of variation (ISCV). For a given water system, the ISCV quantifies the variation of mean arsenic levels at the system's entry points to the distribution system (i.e., sampling points of individual wells and treatment points) around the overall system mean. EPA estimated separate ISCVs for ground water CWS, surface water CWS, and ground water NTNCWS. Each of these ISCVs was assumed to be constant throughout the U.S. EPA used the estimated ISCVs as part of its cost simulation model summarized today in section II.E.

Since the completion of its occurrence analysis for the arsenic rule (EPA 2000h), EPA has received additional occurrence data from one State, North Carolina. More occurrence data from other States may become available in the future.

2. Request for Occurrence Comments

Some stakeholders expressed concern that EPA estimated nationwide occurrence using data from only 25 States, and that the national occurrence estimate was therefore not as reliable as it should have been. Many commenters provided occurrence data about their individual system, which could not be used in the statistical approach. Some commenters suggested that EPA should either request data from all States, or else augment its data set with data from other sources. As noted in EPA's Response-to-Comments document for the January 2001 rule, EPA's occurrence estimates are based on finished water data from States for which data of adequate quality in the range of interest (3–20 μg/L) were available. EPA requests comment on the assumptions, data, methodologies, and results of its occurrence analysis, as well as any new occurrence data that commenters believe EPA should consider in its occurrence assessment. EPA also requests comment on whether it is appropriate to use long-term averages as a proxy for compliance in computing costs for various levels of the standard.

D. How did EPA Evaluate the Health Risks of Arsenic in Drinking Water?

1. Summary of Health Risk Elements

Arsenic ingestion at various levels has been linked to a variety of health effects, both cancerous and non-cancerous. These health effects include cancer of the bladder, lungs, skin, kidney, nasal passages, liver, and prostate. Arsenic ingestion has also been associated with cardiovascular, pulmonary, immunological, neurological, endocrine, and reproductive and developmental effects. In almost all cases, the drinking water levels at which these associations have been found are higher than the current 50 μg/L standard and the levels typically found in U.S. drinking water. Extrapolating these associations down to levels of regulatory interest (i.e., less than 50 μg/L) entails uncertainty and there has been debate among stakeholders over the appropriate methodology for doing so. Of all the studies noted in the report issued by the National Research Council (NRC 1999) and literature reviewed by EPA, the Agency believes that those studies focusing on bladder and lung cancer provide the best basis to quantify dose response relationships and extrapolate these relationships down to the levels of regulatory interest. Therefore, the Agency based its assessment of the quantifiable health risk reduction benefits on the risks of arsenic-induced bladder and lung cancers.

The Agency's approach for the health risk quantitative analysis includes five components. First, EPA developed relative exposure factor (REF) distributions, where the life-long REFs indicate the sensitivity of exposure of an individual relative to the sensitivity of exposure of an ''average'' person weighing 70 kilograms and consuming approximately 2 liters of water per day. These REFs incorporate data from the recent EPA water consumption study (EPA 2000a) with age, sex, and weight data. Second, EPA calculated arsenic occurrence distributions for the population exposed to arsenic levels above 3 μg/L. Third, EPA chose risk distributions for bladder and lung cancer for the analysis from Morales et al. (2000), a peer-reviewed article published in July 2000, which presented additional analyses of bladder cancer risks as well as estimates of lung and liver cancer risks for the same Taiwanese population analyzed in the NRC report. EPA summarized and analyzed the new information from the Morales et al. (2000) article in a Notice of Data Availability (NODA) (EPA 2000e) published on October 20, 2000 (65 FR 63027). Although the data used were the same as used by the NRC to analyze bladder cancer risk in their 1999 publication, Morales et al. (2000) considered more dose-response models and evaluated how well they fit the Taiwanese data, for both bladder cancer risk and lung cancer risk. Fourth, EPA developed estimates of the projected bladder and lung cancer risks faced by exposed populations using Monte-Carlo simulations, bringing together the relative exposure factor, occurrence, and risk distributions. These simulations resulted in upper-bound estimates of the actual risks faced by U.S. populations exposed to arsenic concentrations at or above 3 μg/L in their drinking water. Finally, EPA identified three significant sources of uncertainty and made adjustments to address one of these to derive alternate, lower risk estimates that reflect exposure to arsenic in cooking water and in food in Taiwan. EPA also recognized and considered qualitatively two other sources of uncertainty (e.g., the shape of the dose response curve at low exposure levels and the different health and nutritional status of the Taiwanese study population relative to the typical U.S. population) that it was not able to quantify (see page 7021 of the January 22, 2001 rule) that might also lead to lower risk estimates if it were possible to account for them quantitatively. EPA also indicated, in the preamble to the January 2001 rule, that it believed that its health risk analysis comprised a plausible range of likely risk associated with various concentrations of arsenic in drinking water. This analysis is described in more detail at pages 7001–7009 and 7020–7021 of the January 22, 2001, rule. Finally, EPA considered the non-monetizable benefits associated with avoiding certain adverse health impacts known to be caused by arsenic at higher concentrations, which also may be associated with low level concentrations, which included other nonquantified cancer endpoints and adverse cardiovascular, pulmonary, immunological, neurological, endocrine, reproductive, and developmental effects. EPA listed reductions in these health effects as unquantified benefits in Tables III.E–3 and III.E–7 that listed the monetizable benefits. In moving off the feasible MCL of 3 μg/L, EPA considered the costs and benefits, including the unquantified benefits (66 FR 6976 at 7022 and 7023).

2. Request for Comment on Health Issues

EPA has asked the National Academy of Sciences (NAS) to update the findings and recommendations of the NRC report, Arsenic in Drinking Water (NRC 1999), based on new studies and analyses, including EPA's risk analyses. EPA recognizes that there are a number of uncertainties inherent in its risk analysis that reflect the state of existing science, available research, and the difficulties associated with applying epidemiological data from one

population to another. The NAS, in its 1999 NRC report, and the Science Advisory Board, in its 2000 report (EPA 2000f), highlighted a number of key issues, as have stakeholders who have participated in the arsenic rule development process. EPA requests comment and any additional data that may be available in the following areas:

(1) Are the data from the southwestern Taiwanese studies presented in the NRC report still the most appropriate data set for the dose-response assessment and risk estimation? What are the uncertainties in the data on which the risk estimates are based, and what is the likely effect of these uncertainties on the quantitative risk estimates?

(2) Did EPA's analyses of U.S. risk provide appropriate adjustments for population differences, including factors such as diet, health status, life style (*e.g.,* smoking, cooking water use), when extrapolating from the Taiwanese study population to the U.S. population? Is it possible and appropriate for EPA to make additional quantitative adjustments to account for such differences using existing data?

(3) Part of EPA's analysis requires the determination of an arsenic level that is projected to cause an adverse effect in one per cent of the population (ED_{01}). Is the dose-response analysis conducted by EPA, as well as any available more recent data, adequate for estimating an ED_{01}?

(4) Did EPA's analysis appropriately consider and characterize the available data on mode of action of arsenic, the dose-response information, and the information on uncertainties, when assessing the public health impacts?

(5) Are EPA's risk estimates at 3, 5, 10, and 20 μg/L consistent with available scientific information, including information from new studies?

(6) What is known or can be inferred about the latency period between exposure to arsenic in drinking water and increased incidence of cancer based on existing research?

E. How Did EPA Calculate the National Costs of Compliance With the Arsenic in Drinking Water Rule?

1. Summary of Cost Elements of January 22, 2001 Rule and Record

EPA listed the national cost estimate for the January 22, 2001, rule in Table III.E.1 (66 FR 6976 at 7010). (This information is discussed at greater length in the Technology and Cost document (EPA 2000i) in the record for the January 22, 2001, rule.) The table presented national cost estimates for the MCL of 10 μg/L and the other three options considered in the proposed rule published on June 22, 2000. Treatment costs represent the vast majority of the total national costs for all four MCL options. For the MCL of 10 μg/L, the treatment costs are estimated to be $169.6 million per year using a 3% discount rate and $193 million per year using a 7% discount rate.

In summary, EPA developed the cost of compliance estimate for the arsenic in drinking water rule as follows. The treatment costs were derived using occurrence data, treatment train unit costs, and decision trees. The occurrence data provide the number of systems that would need to install treatment in each size category. The treatment train unit cost estimates provide a measure of how much a technology will cost to install. Decision trees vary by system size and are used as a prediction of the treatment technology trains that facilities would likely install to comply with the options considered for the revised arsenic standard. An analysis of the available treatment trains for arsenic removal and the unit costs for the 13 treatment trains (listed in Exhibits A–7 through A–22 in EPA 2000g) used in the national cost estimate are described in the December 2000 document entitled ''Technologies and Cost for the Removal of Arsenic in Drinking Water'' (EPA 2000i). The decision tree and a description of the model used to calculate the national cost estimate are described in the December 2000 document entitled Arsenic in Drinking Water Rule Economic Analysis (EPA 2000g).

Many of the comments EPA received on the June 2000 proposed rule were on the national cost estimate and the available treatment technologies. EPA reviewed these comments and comments from the Drinking Water Committee of EPA's Science Advisory Board. The January 2001 rule incorporates a number of changes based on these comments, which are discussed in detail in sections V.F and V.G of the preamble (66 FR 6976 at 7034) and are discussed more extensively, in the Technology and Cost document (EPA 2000i). The major changes are summarized in today's document.

EPA received many comments on the proposed rule stating that the Agency did not adequately consider problems with waste generation and disposal when evaluating which technologies would be most appropriately used for achieving compliance. Prior to issuing the arsenic rule, EPA re-examined the 25 treatment trains considered for the proposed rule. The Agency eliminated five treatment trains due to concerns about hazardous waste. The ability to discharge brine streams to publicly owned treatment works (POTWs) was another issue related to waste generation and disposal. Comments indicated that potential increases in total dissolved solids and technically based local limits at the POTW would limit the discharge of brines to POTWs. EPA eliminated brine discharge to POTWs from activated alumina processes as a Best Available Technology due to the arsenic concentration in the brine. EPA also significantly reduced the use of anion exchange with POTW discharge in the decision tree for the January 2001 rule. These issues are discussed in greater detail on pages 7036–7038 of the January 2001 preamble.

The national cost estimate generated a large number of stakeholder comments. Many of these comments stated that EPA underestimated the costs for implementing the proposed rule. Many of these comments referred to the report ''Cost Implications of a Lower Arsenic MCL'' as the basis for their comments. This report (Frey et al. 2000a) was published by the American Water Works Association Research Foundation (AWWARF) in May 2000. The national cost estimates in the AWWARF report were updated in October 2000 (Frey et al. 2000b). For the MCL of 10 μg/L, the October 2000 Update lists a national compliance cost estimate of $345 million per year with no sensitivity considerations (lower bound) and $585 million per year with sensitivity considerations (upper bound). (These upper and lower bound estimates result from different assumptions about cost model input variables.) EPA reviewed the May 2000 AWWARF report and the October 2000 update and summarized factors in the report in detail on pages 7040–7041 of the January 2001 preamble that EPA identified as being key reasons for the differences in cost estimates. These factors include differences in flow rate assumptions, unit costs, and national estimates for arsenic occurrence. The Arsenic Response-to-Comments Document (EPA 2000j) also includes more detail on EPA's review of the national cost estimates in ''Cost Implications of a Lower Arsenic MCL.''

In commenting on the proposed rule, the SAB also expressed concern that the Agency's cost estimates appeared low. The SAB identified two concerns in particular: (1) The assumptions regarding disposal options for brine and other residuals (see discussion in section II. E. 1. of the revision EPA made to address these concerns); and (2)

whether the technologies identified as BAT have been implemented or optimized for arsenic removal at the treatment plant scale, and whether doing so would reduce their effectiveness for the other purpose for which they have been designed, in which case compliance costs could be underestimated.

A Working Group of the National Drinking Water Advisory Council (NDWAC) is reviewing the costing methodologies, assumptions, and information underlying the system-size as well as the aggregated national estimate of system costs of the arsenic rule. As a part of this review, the Working Group is also evaluating significant alternative costing approaches where there is adequate information upon which to evaluate the basis for the alternate estimates or approaches, including the AWWARF cost reports. The group may identify and comment on additional factors affecting these cost estimates (*e.g.,* number of entry points to the distribution system) in addition to those discussed in the January 2001 rule. The NDWAC Working Group will make a recommendation to the full NDWAC based on their review of the national cost estimates.

2. List of Cost Issues and Request for Comments

Specific questions related to the cost of compliance analysis for the arsenic rule on which EPA is interested in receiving public comment include the following:

(1) Did EPA use appropriate ''baseline'' assumptions (*e.g.,* occurrence, co-occurring contaminants, affected systems, entry points, design and average flows, availability of land, in-place treatment)? If not, how could these assumptions be improved and what data would support such revised assumptions?

(2) Did EPA identify an appropriate set of treatment ''trains'' and make appropriate assumptions about the costs of technologies included in those treatment trains as a part of the process of developing national cost estimates? Has EPA identified restrictions that may limit or eliminate treatment technology and residuals management combinations, including the application of treatment technologies to arsenic on a large scale, and integration of arsenic removal with other treatment plant objectives? If not, how could these assumptions and inputs be improved?

(3) Did EPA use an appropriate ''decision tree'' for the final rule? If not, how can that decision tree be improved?

F. How Did EPA Calculate the Benefits of the Arsenic Rule?

1. Summary of the January 22, 2001, Benefits Assessment

Of the various health effects linked to arsenic ingestion, in the January 2001 rule EPA prepared a quantitative assessment of lung and bladder cancer. Other health effects and possible non-health benefits that EPA was unable to quantify were considered qualitatively as required by SDWA, and as discussed in the January 2001 rule.

The process by which EPA analyzed the benefits of reduced bladder and lung cancer cases for the arsenic rule involved several steps. These steps included the calculation of risk reductions, calculation of the number of cancer cases avoided, monetization of avoided bladder and lung cancer cases, qualitative analysis of non-quantifiable benefits, and a sensitivity analysis of benefits estimates to examine the impacts of discounting over a latency period and accounting for other adjustments such as voluntariness and controllability.

Using the risk estimate calculations described in section II.C. of today's notice, EPA calculated the number of bladder and lung cancer cases avoided for CWSs and NTNCWSs (see Table III.D–3, 66 FR 6976 at 7009). Note that EPA derived separate cancer risks for NTNCWSs, as summarized in the preamble to the June 2000 proposal (pages 38952–38956) and described in section 5.3.3 of the Economic Analysis (EPA 2000g). The lower- and upper-bound risk estimates were applied to the exposed population to generate cases avoided for Community Water Systems (CWS) serving fewer than 1 million customers. Since the Agency had arsenic occurrence information for very large systems (those serving greater than one million customers), their system-specific arsenic distributions could be directly computed and cases avoided calculated from these distributions (appendix b.2 in EPA 2000g). In the proposal and January 2001 rule, EPA adjusted the number of bladder cancer cases avoided to reflect a possible lower mortality rate in Taiwan (a lower death rate would increase the number of estimated Taiwanese cases to include more non-fatal cancers) than was assumed in the risk assessment process, which is described in section 5.4.1 of the Arsenic Economic Analysis (EPA 2000g). The Agency adjusted the upper-bound U.S. cancer cases avoided to assume an 80% mortality rate for bladder cancer and 100% fatality for lung cancer in Taiwan. The Agency then divided the U.S. cases avoided into morbidity (non-fatal) and premature fatality cases based on U.S. mortality rates of 26% for bladder cancer and 88% for lung cancer.

In order to monetize the benefits from bladder and lung cancer cases avoided, the Agency used two different values. First, a Value of Statistical Life (VSL) estimate was applied to those cancer cases that result in a mortality. As noted, EPA assumed a 26% mortality rate for bladder cancer and an 88% mortality rate for lung cancer. The current VSL value used by the Agency is $6.1 million, in 1999 dollars (66 FR 6976 at 7012). VSL does not refer to the value of an identifiable life, but rather to the value of small reductions in mortality risks in a population. A ''statistical'' life is thus the sum of small individual risk reductions across an entire exposed population and is not the value for saving a particular individual's life.

Second, EPA used a Willingness to Pay (WTP) value (66 FR 6976 at 7012) to monetize the cancer cases that do not result in a mortality. A WTP value for avoiding a non-fatal cancer is currently not available; therefore the Agency used a WTP estimate to reduce a case of chronic bronchitis as a proxy. The mean value of this WTP estimate is $607,000 in 1999 dollars. A complete discussion of the VSL and WTP values and how they are calculated can be found in Chapter 5 of the Arsenic Economic Analysis (EPA 2000g).

There are also a number of non-quantifiable benefits that EPA considered in its analysis of the benefits for the arsenic rule. Chief among these are certain health impacts identified in various studies involving arsenic levels greater than 50 μg/L. To date, the extent to which these impacts occur at levels below 50 μg/L has not been determined. These additional health effects include other cancers such as skin, kidney, nasal passage, liver, and prostate cancers and non-cancer endpoints such as cardiovascular, pulmonary, immunological, neurological, and endocrine impacts. These health effects and the relevant studies linking these health effects to arsenic in drinking water are discussed in section III.D of the preamble to the rule (66 FR 6976 at 7000). Table III.E–3 in the preamble to the rule (66 FR 6976 at 7012) shows the estimated benefits from reducing arsenic in drinking water for arsenic levels of 3, 5, 10, and 20 μg/L. This table also includes a listing of the potential non-quantifiable benefits associated with reducing arsenic in drinking water.

The Agency also provided a sensitivity analysis on benefits estimates in the rule to examine the impacts of

discounting over a latency period and adjustments for income growth and the nature of the risk (the extent to which the risk is voluntary and controllable). In a July 2000 letter, the EEAC of the SAB recommended that benefits estimates for environmental regulations include adjustments for latency and for income growth in the primary analysis, while adjustments for other factors, such as the extent to which risk is voluntary or controllable, be addressed in a sensitivity analysis. For the arsenic rule, the Agency chose to address all of these factors in a sensitivity analysis because it lacked quantitative data on cancer latency periods associated with arsenic exposure in drinking water. The sensitivity analysis used a range of latencies from 5 to 20 years and discount rates of 3 and 7%. It also adjusted for income growth and included a 7% increase in valuation to account for the lack of voluntariness and controllability of risk. The sensitivity analysis showed that the adjustments to monetized benefits could range from a 10% increase (accounting for income growth only) to a 70% decrease (accounting for income growth, latency, and voluntariness/controllability). The sensitivity analysis did not provide estimates accounting only for latency and income growth. Tables III.E–5 and III.E–6 in the January 2001 preamble illustrate the sensitivity of monetized benefits estimates to different assumptions for latency period duration, discount rate, rate of income growth, and inclusion of a voluntariness and controllability factor. A more detailed description of this analysis is shown in section III.E.2.b of the preamble to the rule (66 FR 6976 at 7012) and Chapter 5 of the Arsenic Economic Analysis (EPA 2000g).

2. List of Key Benefit Analysis Issues

Significant issues associated with the benefits analysis for the arsenic in drinking water rule addressed topics such as the timing of health benefits accrual (latency) and the Agency's consideration of non-quantifiable benefits in its regulatory decision-making process. The Agency requests comments on these and related issues in the following summary.

Specific issues related to the benefits analysis for the arsenic rule include:

a. Discounting benefits over a cancer latency period. The SAB has recommended that EPA should discount its monetized benefits over a cancer latency period (EPA 2000d). A latency period is generally defined as the time between exposure to an environmental carcinogen and the resulting cancer fatality. Precise information on the latency period for most cancers is generally unavailable, but latency periods can be significant. The latency period may also be defined in several different ways. This period can be defined as the time between exposure and the resulting fatality or the time between exposure and onset or diagnosis of the cancer. This definition does not consider the time between exposure and early adverse changes at the cellular level in the body (*i.e.,* before clinical expression of cancer). Definition of the latency period can have a significant impact on the length of time over which benefits are discounted, especially for cancer illnesses where the period of morbidity (*e.g.,* non-fatal illness) is lengthy. EPA has specifically requested the National Academy of Sciences, in their review of the health risks of arsenic in drinking water, to examine this issue in more detail and discuss what is known or can be inferred about the latency period between exposure to arsenic in drinking water and increased incidence of cancer based on existing research.

b. Consideration of non-quantifiable benefits in the regulatory decision-making process. Some stakeholders have argued that EPA did not fully consider the non-quantifiable benefits in its decision-making process for the arsenic rule and that EPA should have performed sensitivity analyses to characterize the potential magnitude of these benefits. Other stakeholders have argued that EPA placed too much emphasis on non-quantifiable benefits in the choice of the arsenic MCL. EPA requests comment on how to handle non-quantifiable benefits in its selection of a final arsenic MCL.

3. Request for Comments on Benefits

(1) How should total benefits and costs and incremental benefits and costs be addressed in the rule in analyzing regulatory alternatives to ensure appropriate consideration by decision makers and the public?

(2) How should latency be addressed in the benefits estimates for the final rule when existing literature does not provide specific quantitative estimates of latency periods associated with exposure to arsenic in drinking water?

(3) Should reduction/elimination of exposure be evaluated as a separate benefits category, in addition to or in conjunction with mortality and morbidity reduction?

(4) How should health endpoints (other than bladder and lung cancer) be addressed in EPA's analysis, when existing literature does not provide specific quantification, to ensure appropriate consideration by decision makers and the public?

(5) How should uncertainties be addressed in EPA's analysis to ensure appropriate consideration by decision makers and the public?

G. What Process Is EPA Planning for Review of Financial, Technical, and Planning Tools for Small Systems?

1. Small System Review Process

As part of its overall review of the arsenic rule, EPA wishes to reassess the financial, technical, and planning tools available to help small systems achieve compliance. SDWA provides special consideration for small systems in a number of areas and also created the Drinking Water State Revolving Fund (DWSRF) to help systems, including small systems, comply with the provisions of the Act. The DWSRF provides low interest loans, and allows forgiveness of principal for communities identified by the States as disadvantaged. The Agency believes that State capacity development strategies offer a useful framework within which to address small system issues. The Agency seeks comment to help it reassess the financial, technical, and planning tools available to small systems and determine what, if any, additional steps the Agency should take to facilitate compliance with a revised arsenic standard.

2. List of Small System Issues

a. Affordability, availability of financial assistance, and treatment technology. Extensive concerns have been raised regarding the ability of households served by small systems to afford compliance with a revised arsenic standard. In the January 2001 rule, the Agency attempted to address many of these concerns. The preamble of the January 2001 rule emphasized the framework established by SDWA to consider affordability and the tools available to help address affordability concerns. These tools include financial assistance; and extended compliance time frames through exemptions. SDWA also provides for small system variances, but EPA determined in the January 2001 rule that affordable small system compliance technologies are available for all categories of system size, so this option is not available for the new arsenic standard published in the January 2001 rule.

The January 2001 preamble points out that about $1 billion/year is being made available to large and small systems through the Drinking Water State Revolving Fund (DWSRF), and about $780 million/year is being made

available through the water and waste disposal program of the Rural Utilities Service (RUS) of the Department of Agriculture. EPA also noted that almost one quarter of the DWSRF loans have been made to systems States classified as disadvantaged (66 FR 6796 at 7020).

Treatment technology is another issue around which small system concerns have clustered. The major concern voiced in this regard has been that small systems may not be able to apply the lower cost compliance technologies identified by EPA. The most significant issue relates to the application of Point-of-Use (POU) technology. Under the arsenic rule, EPA has designated POU technology as an affordable compliance technology. The Agency recognizes that application of POU technology for compliance is not presently a common practice and water systems would face a number of challenges in implementing such an approach. EPA's probability decision trees (Exhibits A–7 through A–22 in the Economic Analysis (EPA 2000g)) assigned POU technologies to approximately 5% of systems serving fewer than 500 in the decision tree. The Agency believes that customers may be quite supportive of a POU solution once they understand the cost-savings it offers based upon pilot studies and information that EPA has analyzed.

b. SDWA Capacity Development Framework. SDWA recognized that small systems would find it more challenging than large systems to achieve the public health protection goals of the Act. In amending SDWA in 1996, Congress found that effective protection of public health requires water systems with adequate managerial, technical, and financial capacity. Congress further found that compliance with the requirements of SDWA continues to be a concern at public water systems experiencing technical and financial limitations; and Federal, State, and local governments need more resources and more effective authority to attain the objectives of SDWA. In response to these findings, Congress included in the amendments a number of provisions designed to help EPA and the States address the needs of small systems, including, for the first time, the State Revolving Loan Fund for assisting drinking water systems in complying with standards.

These provisions included new flexibility for EPA in setting standards and compliance time frames; explicit authority to allow Point-of-Use technologies for compliance; broader and more flexible authority for issuing exemptions to provide systems with additional time to comply; small system variances in cases where EPA determines that affordable small system compliance technologies are not available; and financial assistance through a new drinking water State revolving fund. In order to help focus these and other tools on helping systems develop managerial, technical, and financial capacity, Congress created a strong incentive for States to develop a ''capacity development strategy.'' States were given broad flexibility in designing their strategy, but were required to consider a number of issues including how they would use the authority and resources of SDWA or other means to assist systems in complying with regulations and to encourage the development of partnerships between systems to enhance their capacity.

All States have developed strategies consistent with the SDWA framework. EPA believes that implementation of a revised arsenic standard will be the first major test of these strategies. SDWA clearly anticipated that systems would need to enhance their technical, financial, and managerial capacity in order to achieve the public health protection objectives of the law. The extensive concerns which have been voiced about systems ability to meet a revised arsenic standard serve to confirm the need for such enhancements.

Successful implementation of a revised standard will require that States focus on developing system capacity by fully utilizing the flexibilities available under SDWA. In particular, the Agency believes that appropriate use of these three provisions will be essential:

(1) DWSRF assistance, including principal forgiveness for disadvantaged communities and set-aside funds to assist systems through a State's capacity development strategy.

(2) Exemptions to allow additional time for systems that demonstrate the need for such time to achieve compliance. Such systems of any size can be granted an additional 3 years beyond the compliance date for the revised MCL to achieve compliance, while systems serving <3300 persons can be granted up to 6 additional years beyond that date. This extra time can be used to obtain financial assistance or undertake restructuring or other changes to achieve compliance.

(3) Application of Point-of-Use (POU) technology.

States may wish to utilize their capacity development strategy as a framework within which to plan the most effective utilization of all of the tools available. In addition to the SDWA provisions discussed previously, another important tool is financial assistance available through the United States Department of Agriculture's Rural Utilities Service.

3. Request for Small Systems Comment

EPA invites comments on all aspects of small system compliance with a revised arsenic standard. In particular, the Agency seeks comment on the following issues:

(1) What additional guidance, information, or other assistance, if any, do States need to help them develop and apply system-level affordability criteria (for prioritizing use of drinking water revolving funds in a State; and for determining whether or not to grant exemptions)?

(2) Will exemptions allowing needy systems additional time to achieve compliance be a useful tool? What guidance, information, or other assistance, if any, should EPA make available to States and or systems relative to exemptions?

(3) To what extent can systems lower their compliance costs or enhance their ability to comply by forming partnerships with other systems or otherwise restructuring their operations? What barriers (physical and/or institutional) exist to the formation of these partnerships? What guidance, information, or other assistance, if any, should EPA make available to States and or systems to assist in the formation of system-level partnerships?

(4) What challenges or barriers exist to adoption of POU technology? What do EPA and or the States need to do to facilitate application of POU technology?

(5) What additional guidance, information, or other assistance do States need to help them refine their capacity development strategies to facilitate compliance with a revised arsenic standard?

III. Process To Be Employed After Technical Reviews and Public Comment

A. How Will EPA Notify the Public of Results of the Technical Reviews and the Nature of the Public Comments?

As previously noted, the findings of the expert review panels will be made publicly available. In addition, EPA will publish a notice with a summary of these findings for public comment. The purpose of the notice will be to provide EPA's perspective on the findings of the review of the costs, benefits, and science underlying the arsenic rule. In addition, the notice will summarize comments received on this proposal and EPA's perspective on those comments. Finally, the notice will provide an indication of how the Agency plans to synthesize this

new information with respect to final decisions on the arsenic in drinking water rule. EPA expects that the notice will be published in the Fall of 2001.

B. What Process Will EPA Use To Make Final Decisions on the Rule?

The process of making final decisions on the arsenic in drinking water regulation will involve legal, regulatory, policy, and scientific considerations. The results of the expert panels' reviews and public comment will be significant and important sources of information that will be fully considered by the Agency as it makes a final decision. In making a final decision, EPA will also exercise judgment and discretion based on the record and all applicable legal, regulatory, and policy requirements. EPA expects to make a final decision on how to proceed with the arsenic rule by February 22, 2001, after considering the reviews and public comments.

IV. Administrative Requirements

A. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866, [58 **Federal Register** 51735 (October 4, 1993)] the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector 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 the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that the January 22, 2001, rule is a ''significant regulatory action'' because it will have annual costs of more than $100 million. Because this proposal is an extension of a rulemaking published on January 22, 2001 (66 FR 6976), and is based on the record for that rulemaking, EPA has complied with this Executive Order through the economic analyses prepared for the January 22, 2001, rulemaking. Those analyses were reviewed by OMB. In addition, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the public record for W–99–16–VI.

B. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, ''which are appropriate to the activities of the agency'' after proposing the alternative definition(s) in the **Federal Register** and taking comment (5 U.S.C. 601(3)–(5)). In addition to the above, to establish an alternative small business definition, agencies must consult with the Small Business Administration's (SBA) Chief of Counsel for Advocacy.

For the purposes of assessing the impacts of today's rule on all three categories of small entities, EPA considered small entities to be systems serving 10,000 or fewer customers. In accordance with the RFA requirements, EPA proposed using this alternative definition for all three categories of small entities in the **Federal Register** (63 FR 7605 at 7620; February 13, 1998), requested public comment and consulted with SBA regarding the alternative definition as it relates to small businesses. In the preamble to the final Consumer Confidence Reports (CCR) regulation (63 FR 4511; August 19, 1998), EPA stated its intent to establish this alternative definition for regulatory flexibility assessments under the RFA for all drinking water regulations and has thus used it in this proposed rulemaking.

As noted in the previous section, this proposal is an extension of, and relies on the record of, a previous rulemaking concerning the same regulatory options. In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the original proposed rule, published in the **Federal Register** on June 22, 2000 (EPA 2000b), and convened a Small Business Advocacy Review Panel to obtain advice and recommendations of representatives of the regulated small entities in accordance with section 609(b) of the RFA. A detailed discussion of the Panel's advice and recommendations is found in the Panel Report (EPA 1999). The June 2000 proposed rule presented a summary of the Panel's recommendations (65 FR 38888 at 38963).

As required by section 604 of the RFA, EPA also prepared a final regulatory flexibility analysis (FRFA) for the January 2001 rule (EPA 2001a). The FRFA and the January 2001 arsenic rule's preamble (66 FR 6976 at 7047) addressed the issues raised by public comments on the IRFA, which was part of the regulatory impact analysis for the proposed rule (65 FR 38888 at 38962; EPA 2000b). The FRFA (EPA 2000j) is available for review in the docket. The previous analyses encompass all of the options proposed again today, and as a result, EPA is relying on those analyses for compliance with the RFA for this proposal.

C. Unfunded Mandates Reform Act (UMRA) of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, Tribal, and local governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the

UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that the January 22, 2001, rule contains a Federal mandate that may result in expenditures of $100 million or more for State, Tribal, and local governments, in the aggregate, or the private sector in any one year. Because today's proposal is an extension of the January 2001 arsenic rulemaking and discusses only those options which were fully analyzed in the previous rulemaking, EPA is relying on the record of the January, 2001 rule to provide the analyses required by UMRA. A detailed description of this analysis is presented in EPA's Economic Analysis of the arsenic rule (EPA 2000g) which is included in the Office of Water docket for the arsenic rule, and summarized in the January 2001 preamble (66 FR 6976 at 7049). Through targeting mailing of this notice to entities on the arsenic mailing list, we will continue to solicit State, local, and Tribal access and dialog on the arsenic rule. EPA will also develop a small government agency plan.

D. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule were previously submitted for approval to the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* As noted in previous sections, today's proposal is an extension of a previous rulemaking which analyzed the same options presented today. As a result, EPA is relying on the PRA analyses prepared for the January 2001 rulemaking and its proposal for compliance with the PRA for this rule. OMB has already reviewed and approved the information collection request (ICR) in the previous rulemaking and assigned OMB control number 2040–0231. This action does not impose any additional information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

E. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

EPA's analysis of the NTTAA's application to this rulemaking is described in the June 22, 2000, proposal at 65 FR 38971–38972 and the January 22, 2001, preamble at 66 FR 7051. EPA requests comment on this analysis.

F. Executive Order 12898: Environmental Justice

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agencies' missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. The Agency has considered environmental justice related issues concerning the potential impacts of this action and consulted with minority and low-income stakeholders.

In the preamble to the June 2000 proposal (65 FR 38888 at 38972), EPA noted arsenic concerns raised during the March 12, 1998, environmental justice stakeholder meeting. The issues raised included confusion over units of measure of test results (*i.e.,* ppb and μg/L), effects on sensitive subpopulations (*e.g.,* incidence of diabetes in Tribal communities), infeasibility of regional consolidation, affordable treatments for small systems, increased access to funding, considering regional needs in standard setting, more training, and protection of low income communities. The Agency took these issues into consideration during the development of the January 2001 arsenic rule and the response-to-comments document. The public is invited to comment on EPA's analysis of environmental justice as it relates to today's proposal (which was discussed in the June 2000 proposal and January 2001 rule) and to recommend additional methods to address environmental justice concerns with the approach for treating arsenic in drinking water.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045: ''Protection of Children From Environmental Health Risks and Safety Risks'' (62 FR 19885; April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This proposed rule is not subject to Executive Order 13045 because the Agency does not have reason to believe that the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. Nonetheless, EPA evaluated the environmental health and safety effects of arsenic in drinking water on children as part of the January 2001 rule and its proposal. The public is invited to submit or identify any new peer-reviewed studies and data that assess results of early life exposure to arsenic via ingestion.

H. Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255; August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.''

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, imposes substantial direct compliance costs, and is not required by statute (unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation). EPA also may not issue a regulation that has federalism implications and that preempts State

law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation. If EPA complies by consulting, Executive Order 13132 requires EPA to provide to OMB in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner.

EPA has concluded that this proposed rule will have federalism implications; these are the same federalism implications discussed and analyzed in the June 2000 and January 2001 arsenic rules. EPA provided the Office of Management and Budget (OMB) with a federalism summary impact statement (FSIS) in the preamble to the proposed and final rules. EPA provided the FSIS on page 7052 of the January 2001 rule (66 FR 6976).

I. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249; November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and the Indian tribes.''

This proposed rule may have tribal implications. It may have substantial direct compliance costs on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and the Indian tribes, as specified in Executive Order 13175. As a result of administrative review of the regulation published on January 22, 2001, the Environmental Protection Agency (EPA) is requesting additional comments on the regulatory options via this proposal. In developing the January 2001 rule, EPA consulted with Tribal governments to permit them to have meaningful and timely input into its development, as described in the preamble (66 FR 6976 at 7052). In the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and tribal governments, EPA specifically solicits additional comment on this proposed rule from tribal officials.

J. Consultations With the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with sections 1412 (d) and (e) of SDWA, the Agency discussed or submitted possible arsenic rule requirements to the Science Advisory Board, National Drinking Water Advisory Council (NDWAC), and to the Secretary of Health and Human Services and requested comment from the Science Advisory Board on the arsenic rule, as described in the January 2001 preamble (66 FR 6976 at 7053). In addition, the April 23, 2001 proposed rule (66 FR 20580) outlines the additional consultations planned with NDWAC. EPA will continue contacts with the Department of Health and Human Services during the arsenic rule review process.

K. Likely Effect of Compliance With the Arsenic Rule on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of SDWA as amended requires that, in promulgating a National Primary Drinking Water Regulation (NPDWR), the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, financial, and managerial capacity of public water systems. EPA provided the analysis performed to fulfill this statutory obligation for the January 2001 rule (EPA 2000a). During this reconsideration process, EPA will review the capacity issues further.

L. Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355; May 22, 2001), provides that agencies shall prepare and submit to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, a Statement of Energy Effects for certain actions identified as ''significant energy actions.'' Section 4(b) of Executive Order 13211 defines ''significant energy actions'' as ''any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) that is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.''

We have not prepared a Statement of Energy Effects for this proposed rule because this rule is not a significant energy action, as defined in Executive Order 13211. While this rule is a significant regulatory action under Executive Order 12866, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

V. References

Chiou, H.-Y., S.-T. Chiou, Y.-H. Hsu, Y.-L. Chou, C.-H. Tseng, M.-L. Wei, and C.-J. Chen. 2001. Incidence of transition cell carcinoma and arsenic in drinking water: A follow-up study of 8,102 residents in an arsenic-endemic area in Northeastern Taiwan. American Journal of Epidemiology. 153:411–418.

Frey, M. M. and M. A. Edwards. 1997. Surveying Arsenic Occurrence. Journal of the American Water Works Association. 89(3):105–117.

Frey, M., J. Chwirka, S. Kommineni, and Z. Chowdhury. 2000a. ''Cost Implications of a Lower Arsenic MCL''. May 5, 2000. American Water Works Association Research Foundation, Denver, CO.

Frey, M., J. Chwirka, S. Kommineni, and Z. Chowdhury. 2000b. ''Update Cost Implications of a Lower Arsenic MCL''. October 10, 2000.

Morales, K.H., L. Ryan, T.-L. Kuo, M.-M. Wu and C.-J. Chen. 2000. Risk of internal cancers from arsenic in drinking water. Environmental Health Perspectives 108:655–661.

National Research Council. 1999. *Arsenic in Drinking Water.* Washington, DC. National Academy Press.

US EPA. 1996. Proposed Guidelines for Carcinogenic Risk Assessment; Notice. **Federal Register**. Vol 61, No. 79, p. 17960. April 23, 1996.

US EPA. 1998a. National Primary Drinking Water Regulations: Consumer Confidence Reports. Final Rule. **Federal Register**. Vol. 63, No. 160, p. 44512. August 19, 1998.

US EPA. 1998b. Benefits Working Group Report to the National Drinking Water Advisory Council, unpublished. October 29, 1998.

US EPA. 1999. Analytical Methods Support Document for Arsenic in Drinking Water. Prepared by Science Applications International Corporation under contract with EPA. December 1999. EPA–815-R–00–010. Available on web at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2000a. Estimated Per Capita Water Ingestion in the United States: Based on Data Collected by the United States Department of Agriculture's (USDA) 1994–1996 Continuing Survey of Food Intakes by Individuals. Office of Water, Office of Standards and Technology. EPA–822–00–008. April 2000.

US EPA. 2000b. National Primary Drinking Water Regulations; Public Notification Rule; Final Rule. **Federal Register**. Vol. 65, No. 87, p. 25982. EPA 815-Z-00–001. May 4, 2000. Available on web at *www.epa.gov/safewater/pn.html.*

US EPA. 2000c. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Proposed Rule. **Federal Register**. Vol. 65, No. 121, p. 38888. EPA 815-Z-00–004 June 22, 2000. Available on web at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2000d. SAB Report from the Environmental Economics Advisory Committee (EEAC) on EPA's White Paper ''Valuing the Benefits of Fatal Cancer Risk Reduction. EPA-SAB-EEAC–00–013. July 27, 2000.

US EPA. 2000e. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Notice of Data Availability. **Federal Register**. Volume 65, Number 204. October 20, 2000. Page 63027–63035. Available on web at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2000f. Arsenic Proposed Drinking Water Regulation: A Science Advisory Board Review of Certain Elements of the Proposal. EPA-SAB-DWC–1–001. December 12, 2000. Available on web at *www.epa.gov/sab.*

US EPA. 2000g. Arsenic Economic Analysis. Prepared by Abt Associate for Office of Ground Water and Drinking Water. EPA 815-R–00–026 December 2000. Available on web at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2000h. Arsenic Occurrence in Public Drinking Water Supplies. Prepared by ISSI for EPA Office of Ground Water and Drinking Water. EPA 815-R–00–023. December 2000. Available online at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2000i. Arsenic Technologies and Costs for the Removal of Arsenic from Drinking Water. EPA 815-R–00–028. December 2000. Available on web at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2000j. Arsenic Response-to-Comments Document for W–99–16-III. December 2000.

US EPA. 2000k. Final Regulatory Flexibility Analysis (FRFA) for the Final Arsenic Rule. December 29, 2000.

US EPA. 2000l. SAB Report on EPA's White Paper, Valuing the Benefits of Fatal Cancer Risk Reduction. EPA-SAB-EEAC–00–013. July 27, 2000. Available on web at *www.epa.gov/sab/eeacf013.pdf.*

US EPA. 2001a. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final Rule. **Federal Register**. Vol. 66, No. 14, p. 6976. EPA 815-Z-01–001. January 22, 2001. Available on web at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2001b. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final Rule; delay of effective date. **Federal Register**. Vol. 66, No. 57, p. 16134. March 23, 2001. Available on web at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2001c. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Notice of proposed rulemaking. **Federal Register**. Vol. 66, No. 78, p. 20580. April 23, 2001. Available on web at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2001d. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Notice; request for nominations to the Arsenic Cost Working Group of the National Drinking Water Advisory Council. Vol. 66, No. 87, p. 22661. May 4, 2001. Available on web at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2001e. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final rule; delay of effective date. **Federal Register**. Vol. 66, No. 99, p. 28342. May 22, 2001. Available on web at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2001f. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Notice [of NDWAC Arsenic Cost Working Group meeting]. Vol. 66, No. 99, p. 28161. May 22, 2001. Available on web at *www.epa.gov/safewater/arsenic.html.*

US EPA. 2001g. Arsenic Response-to-Comments Document for W–99–16-IV. May 2001.

US EPA. 2001h. Meetings of the Arsenic Cost Working Group of the National Drinking Water Advisory Council; Notice of Public Meeting. Vol. 66, No. 116, p. 32617. June 15, 2001.

US EPA. 2001i. EPA Science Advisory Board; Notification of Public Advisory Committee Meetings. Vol. 66, No. 127, p. 34924. July 2, 2001.

WH. 2001. Memorandum for the Heads and Acting Heads of Executive Departments and Agencies. **Federal Register**. Vol. 66, No 66, pg. 7702. January 24, 2001. Available on web at *www.epa.gov/safewater/arsenic.html.*

US GS. 2000. Focazio, M., A. Welch, S. Watkins, D. Helsel & M. Horn. A retrospective analysis of the occurrence of arsenic in ground water resources of the United States and limitations in drinking water supply characterizations. Water Resources Investigations Report: 99–4279. May 2000. Available on web at: http://co.water.usgs.gov/trace/arsenic.

List of Subjects in 40 CFR Parts 141 and 142

Environmental protection, Chemicals, Indian lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: July 13, 2001.

Christine Todd Whitman,

Administrator.

[FR Doc. 01–18093 Filed 7–18–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 98–67; DA 01–1555]

Provision of Improved Telecommunications Relay Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document solicits additional comment on the provision of improved Telecommunications Relay Service (TRS). Title IV of the Americans with Disabilities Act (ADA) requires the Commission to promulgate regulations on TRS, to make available to Americans with hearing or speech disabilities telecommunications services that are functionally equivalent to those available to individuals without disabilities.

DATES: Comments are due on or before July 30, 2001 and reply comments are due on or before August 6, 2001.

ADDRESSES: Federal Communications Commission, 445 12th Street, S.W, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Dana Jackson, (202) 418–2247 (voice), (202) 418–7898 (TTY). This document is available to individuals with disabilities requiring accessible formats (electronic ASCII text, Braille, large print, and audio) by contacting Brian Millin at (202) 418–7426 (voice), (202) 418–7365 (TTY), or by sending an email to *access@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Bureau is issuing this document to seek comment on WorldCom's Petition and additional issues associated with IP Relay. Comments already submitted in response to WorldCom's petition will be

considered in this docket. All comments shall reference the docket number of this proceeding. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. Comments filed through ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html*. In completing the transmittal screen, commenters should include their full name, postal service mailing address, and the docket number of this proceeding. Parties who choose to file by paper must file an original and four copies of each filing with the Commission's Secretary (Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 12th Street, SW., Washington DC 20554) and a diskette copy to the Commission's copy contractor (International Transcription Service, Inc. (ITS), CY–B400, Federal Communications Commission, 445 12th Street, SW., Washington DC 20554). In addition, parties must submit a paper copy and diskette to Dana Jackson, Disabilities Rights Office, Consumer Information Bureau, Federal Communications Commission, Room 4–C746, 445 12th Street, SW., Washington DC 20554. Filings and comments are also available for inspection and copying during business hours in the Reference Information Center, Federal Communications Commission, Room CY–A257, 445 12th Street, SW., Washington DC or may be purchased from ITS. Pursuant to 47 CFR 1.1206, this proceeding will be conducted as a permit-but-disclose proceeding in which *ex parte* communications are permitted subject to disclosure.

Synopsis

In its *First Report and Order* on TRS, (56 FR 36729, August 1, 1991) the Commission established minimum operational, technical, and functional standards to fulfill this mandate. Last year, the Commission released additional minimal standards to supplement these earlier standards. Specifically, in its *Improved TRS Order and FNPRM,* (65 FR 38490, June 21, 2000) the Commission both expanded the scope of eligible services that would be classified to receive reimbursement as relay services, and established new criteria for relay providers to improve the quality of relay services. Among other things, the *Improved TRS Order and FNPRM* added speech-to-speech (STS) and interstate Spanish relay as required relay offerings, and permitted the recovery of video relay service (VRS) costs through the interstate TRS funding mechanism. The Order encouraged, but did not require the provision of VRS at the present time. On December 22, 2000, WorldCom filed a Petition for Clarification of the *Improved TRS Order and FNPRM* (Petition) seeking clarification that its connection to TRS via the Internet (IP Relay) is eligible for reimbursement from the Interstate TRS Fund. On May 8, 2001, representatives from WorldCom met with Commission staff to further discuss WorldCom's petition. *See, Ex parte* letter from Larry Fenster, WorldCom, to Magalie Salas, Secretary, Federal Communications Commission, dated May 9, 2001. Additionally, on May 18, 2000, representatives from Communications Services for the Deaf made a presentation to Commission staff on its for a similar IP-based relay service. *See, Ex parte* letter from Philip W. Bravin, Communications Services for the Deaf, to Magalie Salas, Secretary, Federal Communications Commission, dated May 23, 2001. Although the information gathered at these meetings, together with the formal comments submitted in response to both the *Improved TRS Order and FNPRM* and the informal comments submitted in response to the WorldCom petition have provided the Commission with basic information about IP Relay, it has become clear that additional information is needed before the Commission can issue a final order on this subject.

Consumer Information Bureau.

Karen Peltz Strauss,

Deputy Chief.

[FR Doc. 01–18054 Filed 7–18–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA No. 01–1578, MM Docket No. 01–144, RM–10142]

Radio Broadcasting Services; Snyder, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Charles Crawford requesting the allotment of Channel 237C3 at Snyder, Texas. The coordinates for Channel 237C3 at Snyder are 32–42–25 and 101–05–36. There is a site restriction 17.2 kilometers (10.7 miles) west of the community.

DATES: Comments must be filed on or before August 27, 2001, and reply comments on or before September 11, 2001.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC. 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, as follows: Charles Crawford, 4553 Bordeaux Avenue, Dallas, Texas 75205; Katherine Pyeatt, 6655 Aintree Circle, Dallas, Texas 75214.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 01–144, adopted June 27, 2001, and released July 6, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Information Center, 445 Twelfth Street, SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800, facsimile (202) 857–3805.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Channel 237C3 at Snyder.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 01–18050 Filed 7–18–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–1593; MM Docket No. 01–147; RM–10162]

Radio Broadcasting Services; George West, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rule making filed by Katherine Pyeatt, requesting the allotment of Channel 292A to George West, Texas, as that community's third local FM transmission service. This proposal requires a site restriction 12.7 kilometers (7.9 miles) west of the community at coordinates 28–20–33 NL and 98–14–45 WL. Additionally, as George West, Texas, is located within 320 kilometers (199 miles) of U.S.-Mexico border, concurrence of the Mexican government to this proposal is required.

DATES: Comments must be filed on or before August 27, 2001, and reply comments on or before September 11, 2001.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: Katherine Pyeatt, 6655 Aintree Circle, Dallas, Texas 75214.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking, MM Docket No. 01–147, adopted June 27, 2001, and released July 6, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center (Room CY–A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Channel 292A, George West, Texas.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 01–18051 Filed 7–18–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–1602; MM Docket No. 01–149; RM–10173]

Radio Broadcasting Services; Savoy, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on the proposed allotment of Channel 297A to Savoy, Texas, as that community's first local aural transmission service. Coordinates used for this proposal are 33–42–58 NL and 96–24–09 WL.

DATES: Comments must be filed on or before August 27, 2001, and reply comments on or before September 11, 2001.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, as follows: The Office of Dan J. Alpert; 2120 N. 21st Road; Arlington, Virginia 22201.

FOR FURTHER INFORMATION CONTACT: R. Barthen Gorman, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 01–149, adopted June 27, 2001, and released July 6, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center (Room CY–A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Savoy, Channel 297A.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 01–18052 Filed 7–18–01; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[I.D. 070901B]

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits (EFPs)

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

ACTION: Notification of a proposal for EFPs to conduct experimental fishing; request for comments.

SUMMARY: NMFS announces that the Administrator, Northeast Region, NMFS (Regional Administrator), has determined that an application for EFPs contains all of the required information and warrants further consideration. The Regional Administrator has also made a preliminary determination that the activities authorized under the EFP would be consistent with the goals and objectives of the Northeast Multispecies Fishery Management Plan (FMP), and the cumulative impacts would be within the scope of earlier analyses on the FMP. However, further review and consultation may be necessary before a final determination is made to issue EFPs. Therefore, NMFS announces that the Regional Administrator proposes to issue EFPs in response to the application that would allow up to 20 vessels to conduct fishing operations otherwise restricted by the regulations governing the fisheries of the northeastern United States. Such fishing operations would continue the collection of data on bycatch of regulated multispecies and would provide information to NMFS and the New England Fishery Management Council regarding whether or not the fishery may be made an exempted fishery under the Northeast Multispecies regulations. The Massachusetts Division of Marine Fisheries (MADMF) has submitted an application for EFPs for commercial otter trawl vessels using the raised footrope trawl. The EFPs would allow the federally permitted vessels to fish with the modified otter trawl with mesh less than the minimum mesh size within a portion of the Gulf of Maine/Georges Bank Regulated Mesh Area. Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed EFPs.

DATES: Comments on this notification must be received at the appropriate address or fax number (see **ADDRESSES**) on or before August 3, 2001.

ADDRESSES: Written comments should be sent to Patricia Kurkul, Regional Administrator, NMFS, Northeast Regional Office, One Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on Raised Footrope Trawl EFP Proposal.'' Comments may also be sent via facsimile (fax) to (978) 281–9135.

FOR FURTHER INFORMATION CONTACT: Peter W. Christopher, Fishery Policy Analyst, 978–281–9288.

SUPPLEMENTARY INFORMATION: MADMF submitted a proposal on May 18, 2001, for EFPs for up to 20 vessels to fish with a modified small-mesh otter trawl for silver hake (*Merluccius bilinearis*) in a portion of the Gulf of Maine/Georges Bank Regulated Mesh Area. The proposed experiment is a continuation of an experimental fishery conducted in 1999 and 2000 to gather information on bycatch retained by the modified otter trawl in the requested area. The experiment proposes to continue the collection of data to determine whether or not the fishery has a level of bycatch of regulated multispecies that would enable the fishery to be determined an exempted fishery under the criteria set forth in the FMP. Based on the outcome of this EFP, this action may lead to future rulemaking.

The study would occur from September 1 through December 30, 2001, and take place east of Cape Cod in an area defined by the following coordinates:

Area Point	N. Latitude	W. Longitude
RFT1	42°14.05′	70°08.80′
RFT2	42°09.20′	69°47.80′
RFT3	41°54.85′	69°35.20′
RFT4	41°41.50′	69°32.85′
RFT5	41°39.00′	69°44.30′
RFT6	41°45.60′	69°51.80′
RFT7	41°52.30′	69°52.55′
RFT8	41°55.50′	69°53.45′

The maximum number of vessels participating in the experiment at a given time would be 20 with an estimated total number of trips at approximately 200. The gear to be used during the experiment is a modified small-mesh otter trawl called the ''raised footrope trawl.'' The gear uses modifications of the float configuration, headrope, footrope, and sweep to keep the mouth of the net from fishing on the bottom and retaining bottom-dwelling species such as flounders, monkfish, skates, lobster, and crabs. Participating vessels would also be subject to a minimum mesh size of 2.5 inches (6.35 cm) in the codend and would be allowed to retain a maximum of 7,500 lb (3,402 kg) of silver hake and offshore hake (*Merluccius albidus*) with nets of mesh size between 2.5 inches (6.35 cm) and 3 inches (7.62 cm), and a maximum of 30,000 lb (13,608 kg) of silver hake and offshore hake with nets of mesh size 3 inches (7.62 cm) and above. The possession limits are to ensure that the conservation goals for whiting are preserved. Vessels may be required to carry onboard observers as requested by MADMF and/or NMFS. Onboard observers will be trained in the protocols of the experiment by MADMF and/or NMFS.

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

Dated: July 13, 2001.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–18105 Filed 7–18–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[I.D. 071001F]

RIN 0648–AO51

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Shrimp Fishery of the Gulf of Mexico; Fishery Management Plan

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

ACTION: Notice of availability; request for comments.

SUMMARY: NMFS announces that the Gulf of Mexico Fishery Management Council (Council) has submitted Amendment 11 to the Fishery Management Plan (FMP) for the Shrimp Fishery of the Gulf of Mexico (Amendment 11) to NMFS for review, approval, and implementation. Amendment 11 would require all shrimp vessels harvesting shrimp in the Gulf of Mexico exclusive economic zone (EEZ) to obtain an annually renewable Federal shrimp vessel permit from NMFS and would prohibit the use of traps in the royal red shrimp fishery of the Gulf of Mexico. Written comments are requested from the public.

DATES: Written comments must be received on or before September 17, 2001.

ADDRESSES: Comments must be mailed to the Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702. Comments may also be sent via fax to 727–522–5583. Comments will not be accepted if submitted via e-mail or Internet.

Copies of Amendment 11, which includes an Environmental Assessment, a Regulatory Impact Review, and an Initial Regulatory Flexibility Analysis are available from the Gulf of Mexico Fishery Management Council, The Commons at Rivergate, 3018 U.S. Highway 301 North, Suite 1000, Tampa, FL 33619–2266. phone: 813–228–2815; fax: 813–833–1844.

Written comments regarding the collection-of-information (e.g., permits) requirements contained in this document may be submitted to Robert Sadler, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (Attention: NOAA Desk Officer).

FOR FURTHER INFORMATION CONTACT: Dr. Steven Branstetter, 727–570–5305; fax 727–570–5583; e-mail: *steve.branstetter&noaa.gov*.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires each Regional Fishery Management Council to submit any fishery management plan (FMP) or amendment to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP or amendment, immediately publish a document in the **Federal Register** stating that the FMP or amendment is available for public review and comment.

The shrimp fishery is the largest fishery in terms of numbers of fishing vessels and participants in the Gulf of Mexico, but is one of the few federally managed fisheries with no fishing permit requirement. Currently, there are limited data available to estimate the number of shrimp fishing vessels and fishing effort expended by those vessels in the Gulf of Mexico EEZ. Amendment 11 would require all shrimp vessels harvesting shrimp in the Gulf of Mexico EEZ to obtain an annually renewable Federal shrimp vessel permit from NMFS. In proposing this action, the Council concluded that information collected via a Federal permit system would aid in the formulation of sound management measures for the shrimp fishery and for those finfish fisheries that are impacted because of the bycatch and bycatch mortality attributable to the shrimp fishery.

Royal red shrimp have been a small component of the Gulf of Mexico shrimp fishery since the early 1960s, traditionally being fished by vessels using modified shrimp trawls at depths exceeding 100 fathoms (183 meters). The Council concluded that allowing trap gear to be used in this fishery would likely lead to gear conflicts and could lead to overfishing. At the Council's request, NMFS implemented an emergency interim rule prohibiting the use of trap gear in the royal red shrimp fishery within the EEZ of the Gulf of Mexico that was promulgated on September 19, 2000 (65 FR 56500), and was extended until September 14, 2001 (66 FR 14862, March 14, 2001).

A proposed rule that would implement measures contained in Amendment 11 has been received from the Council. In accordance with the Magnuson-Stevens Act, NMFS is evaluating the proposed rule to determine whether it is consistent with the FMP, the Magnuson-Stevens Act, and other applicable law. If that determination is affirmative, NMFS will publish the proposed rule in the **Federal Register** for public review and comment.

Comments received by September 17, 2001, whether specifically directed to the FMP or the proposed rule, will be considered by NMFS in its decision to approve, disapprove, or partially approve Amendment 11. Comments received after that date will not be considered by NMFS in this decision. All comments received by NMFS on Amendment 11 or its proposed rule during their respective comment periods will be addressed in the final rule.

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

Dated: July 13, 2001.

Bruce C. Morehead

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–18104 Filed 7–18–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 622 and 640

[I.D. 020801A]

RIN 0648–AN83

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Amendment to the Fishery Management Plans of the Gulf of Mexico

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

ACTION: Notice of availability; request for comments.

SUMMARY: NMFS announces that the Gulf of Mexico Fishery Management Council (Gulf Council) has submitted for review, approval, and implementation under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) those measures of its Generic Amendment Addressing the Establishment of the Tortugas Marine Reserves in the Fishery Management Plans of the Gulf of Mexico (Generic Tortugas Amendment) that would amend the Fishery Management Plan for Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic and the Fishery Management Plan for the Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic. The Generic Tortugas Amendment would establish two marine reserves in the exclusive economic zone in the vicinity of the Dry Tortugas, FL. Within the marine reserves, fishing for any species and anchoring by fishing vessels would be prohibited. The intended effect is to protect and conserve important marine resources. NMFS previously approved those measures of the Generic Tortugas Amendment that amend the Gulf Council's other fishery management plans (FMPs).

DATES: Written comments must be received on or before September 17, 2001.

ADDRESSES: Written comments on the subject measures of the Generic Tortugas Amendment must be sent to Michael Barnette, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702. Comments may also be sent via fax to 727–570–5583. Comments will not be accepted if submitted via e-mail or the Internet.

Requests for copies of the Generic Tortugas Amendment, which includes a regulatory impact review and a final supplemental environmental impact statement, should be sent to the Gulf of Mexico Fishery Management Council, 3018 U.S. Highway 301 North, Suite 1000, Tampa, FL 33619-2266; phone: 813–228–2815; fax: 813–225–7015; e-mail: gulf.council&noaa.gov.

FOR FURTHER INFORMATION CONTACT: Michael Barnette, NMFS; phone: 727–570–5305; fax: 727–570–5583; e-mail: Michael.Barnette&noaa.gov.

SUPPLEMENTARY INFORMATION: The Gulf Council previously submitted its Generic Tortugas Amendment to NMFS for Secretarial review, approval, and implementation. A notice of its availability for public comment was published in the **Federal Register** on March 7, 2001 (66 FR 13692). On June 6, 2001, NMFS approved those management measures in the Generic Tortugas Amendment that amend the following FMPs: Fishery Management Plan for Coral and Coral Reefs of the Gulf of Mexico; Fishery Management Plan for the Red Drum Fishery of the Gulf of Mexico; Fishery Management Plan for the Stone Crab Fishery of the Gulf of Mexico; Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico; and Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico.

The amendment's proposed management measures that would amend the two FMPs prepared jointly (joint FMPs) by the Gulf Council and the South Atlantic Fishery Management Council (South Atlantic Council), namely the Fishery Management Plan for Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic and the Fishery Management Plan for the Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic, had yet to be adopted by the South Atlantic Council. Therefore, those amendment measures proposed for amending the two joint FMPs were not eligible for Secretarial review and approval under the Magnuson-Stevens Act at the time the Gulf Council first submitted the amendment to NMFS for Secretarial review.

At its meeting of June 18-23, 2001, the South Atlantic Council adopted the amendment's proposed management measures that would amend the two joint FMPs. Based on this action by the South Atlantic Council, NMFS has determined that the amendment's measures that would amend the two joint FMPs have been properly submitted for Secretarial review by the Gulf Council and can now be reviewed and, if approved, implemented. Accordingly, NMFS is publishing this notice of availability of these amendment measures for public comment.

To date, NMFS has not published a proposed rule for the Generic Tortugas Amendment. In accordance with the Magnuson-Stevens Act, NMFS is evaluating the proposed rule to determine whether it is consistent with the Generic Tortugas Amendment, the Magnuson-Stevens Act, and other applicable law. If that determination is affirmative, NMFS will publish the proposed rule in the **Federal Register** for public review and comment. The proposed rule will include amendment measures approved by NMFS on June 6, 2001, for the following FMPs: Fishery Management Plan for Coral and Coral Reefs of the Gulf of Mexico; Fishery Management Plan for the Red Drum Fishery of the Gulf of Mexico; Fishery Management Plan for the Stone Crab Fishery of the Gulf of Mexico; Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico; and Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico. The proposed rule will also include those proposed management measures for amending the two joint FMPs that are the subject of this notice. These latter measures would amend the Fishery Management Plan for Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic and the Fishery Management Plan for the Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic.

Considerable background information on the Generic Tortugas Amendment is contained in the original notice of availability published March 7, 2001 (66 FR 13692) and is not repeated here. Under the Generic Tortugas Amendment, the Gulf Council proposes that the marine reserves be established for a period of at least 10 years, during which the ecological benefits of the reserves will be evaluated. The prohibition on fishing and anchoring of fishing vessels should minimize human disturbances in the Tortugas reserves and help to restore and maintain their ecological integrity, including a full assemblage of fish, coral, and other benthic invertebrates. The reserves will also create a reference or baseline area for studying human impacts on coral reef ecosystems.

Comments received by September 17, 2001, whether specifically directed to those management measures in the Generic Tortugas Amendment that would amend the joint FMPs or to the proposed rule, will be considered by NMFS in its decision to approve, disapprove, or partially approve those measures amending the joint FMPs. Comments received after that date will not be considered by NMFS in this decision. All comments received by NMFS on the Generic Tortugas Amendment (under both the current and previous Secretarial review periods) or the proposed rule during their respective comment periods will be addressed in the preamble of the final rule.

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

Dated: July 12, 2001.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–17937 Filed 7–18–01; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 66, No. 139
Thursday, July 19, 2001

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 COMMERCE

Rural Housing Service, et al.

Request for Reinstatement of a Previously Approved Information Collection

AGENCIES: Rural Housing Service, Rural Business-Cooperative Service, Rural Utilities Service, and Farm Service Agency, USDA.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agencies' intention to request reinstatement of a previously approved information collection in support of the Agencies' use of supervised bank accounts (SBA).

DATES: Comments on this notice must be received by September 17, 2001 to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: James E. Vollmer, Senior Loan Specialist, Multi-Family Housing Portfolio Management Division, RHS, STOP 0782, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250–0782. Telephone: (202) 720–1060.

SUPPLEMENTARY INFORMATION:

Title: 7 CFR 1902–A, Supervised Bank Accounts.

OMB Number: 0575–0158.

Type of Request: Reinstatement of information collection.

Abstract: The Agencies extend financial assistance to applicants that do not qualify for loans under commercial rates and terms.

The Agencies use SBAs as a temporary mechanism to (1) ensure correct disbursement and expenditure of all funds designated for a project; (2) help a borrower properly manage its financial affairs; and (3) ensure that the Government's security is protected adequately from fraud, waste, and abuse.

SBAs are mandatory for Multi-Family Housing (MFH) reserve accounts. The MFH funds must be kept in the SBA for the full term of a loan. Any funds withdrawn for disbursement for an authorized purpose require a countersignature from an Agency official.

This regulation prescribes the policies and responsibilities for the use of SBAs. In carrying out their mission as a supervised credit Agency, this regulation authorizes the use of supervised accounts for the disbursement of funds. The use may be necessitated to disburse Government funds consistent with the various stages of any development (construction) work actually achieved. On limited occasions, a supervised account is used to provide temporary credit counseling and oversight of those being assisted who demonstrate an inability to handle their financial affairs responsibly. Another use is for depositing multi-housing reserve account funds in a manner requiring Agency co-signature for withdrawals. Multi-housing reserve account funds are held in a sinking fund for the future capital improvement needs for apartment projects. Supervised accounts are established to ensure Government security is adequately protected against fraud, waste, and abuse.

The legislative authority for requiring the use of supervised accounts is contained in Section 339 of the Consolidated Farm and Rural Development Act (CON ACT), as amended (7 U.S.C. 1989), and Section 510 of the Housing Act of 1949, as amended (42 U.S.C. 1480). These provisions authorize the Secretary of Agriculture to make such rules and regulations as deemed necessary to carry out the responsibilities and duties the Government is charged with administering.

Estimate of Burden: Public reporting burden for this information collection is estimated to average .42 hours per response.

Respondents: The primary respondents are small businesses.

Estimated Number of Respondents: 20,000.

Estimated Number of Responses per Respondent: 3.1.

Estimated Number of Responses: 62,000.

Estimated Total Annual Burden on Respondents: 26,040 hours.

Copies of this information collection can be obtained from Tracy Gillin, Regulations and Paperwork Management Branch, at (202) 692–0039.

Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agencies, including whether the information will have practical utility; (b) the accuracy of Agencies' estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Tracy Gillin, Regulations and Paperwork Management Branch, U.S. Department of Agriculture, Rural Development, STOP 0742, 1400 Independence Ave. SW., Washington, DC 20250. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

July 11, 2001.

John W. Williams,

Acting Administrator, Farm Service Agency.

July 12, 2001.

Blaine D. Stockton,

Acting Administrator, Rural Utilities Service.

July 12, 2001.

James C. Alsop,

Acting Administrator, Rural Housing Service.

July 13, 2001.

William F. Hagy III,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. 01–18064 Filed 7–18–01; 8:45 am]

BILLING CODE 3410–XV–U

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 32–2001]

Foreign-Trade Zone 15—Kansas City, MO, Area Application for Expansion

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Greater Kansas City Foreign Trade Zone, Inc., grantee of Foreign-Trade Zone 15, requesting authority to expand its zone in the Kansas City, Missouri, area, adjacent to the Kansas City, Missouri, Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on July 6, 2001.

FTZ 15 was approved on March 23, 1973 (Board Order 93, 38 FR 8622, 4/4/73) and expanded on October 25, 1974 (Board Order 102, 39 FR 39487, 11/7/74); February 28, 1996 (Board Order 804, 61 FR 9676, 3/11/96); May 31, 1996 (Board Order 824, 61 FR 29529, 6/11/96); December 8, 1997 (Board Order 934, 62 FR 65654, 12/15/97); October 19, 1998 (Board Order 1004, 63 FR 59761, 11/5/98); January 8, 1999 (Board Order 1016, 64 FR 3064, 1/20/99) and, June 17, 1999 (Board Order 1042, 64 FR 34188, 6/25/99). The zone project includes 8 general-purpose sites in the Kansas City, Missouri, port of entry area: *Site 1* (250,000 sq. ft.)—Midland International Corp. warehouse, 1690 North Topping, Kansas City; *Site 2* (2,815,000 sq. ft.)—Hunt Midwest surface/underground warehouse complex, 8300 N.E. Underground Drive, Kansas City; *Site 3* (10,000 acres)—Kansas City International Airport complex, Kansas City; *Site 4* (416 acres)—Surface/underground business park (Carefree Industrial Park), 1600 N.M–291 Highway, Sugar Creek; *Site 5* (5.75 million sq. ft.)—CARMAR Underground Business Park and Surface Industrial Park (1,000 acres) located at No. 1 Civil War Road, Carthage; *Site 6* (28,000 sq. ft., 11 acres)—Laser Light Technologies, Inc., Hermann Industrial Park, 5 Danuser Drive, Hermann; *Site 7* (1,750 acres)—Richards-Gebaur Memorial Airport Industrial Park complex, 1540 Maxwell, Kansas City; and *Site 8* (169 acres, 3 parcels)-*Site 8a* (60,000 sq. ft., 4 acres)—warehouse facility of Midwest Quality Glove, Inc., 835 Industrial Road, Chillicothe; *Site 8b* (11 acres)—Chillicothe-Brunswick Rail Yard, Washington Street, Chillicothe; and *Site 8c* (50,000 sq. ft., 154 acres)—Chillicothe Industrial Park, Corporate Road, Chillicothe.

The applicant is now requesting authority to further expand the general-purpose zone to include two additional sites (50 acres) in St. Joseph, Missouri: *Proposed Site 9* (200,000 sq. ft., 25 acres)—public storage facility at 2307 Alabama, St. Joseph; and, *Proposed Site 10* (169,000 sq. ft., 25 acres)—public storage facility at 2326 Lower Lake Road, St. Joseph. Some 900,000 sq. ft. of additional warehouse space is planned for the two sites. Both sites will be operated by Pony Express Warehousing, Inc. They are owned by two related companies, L & A Development, L.L.C. and Lower Lake Road, L.L.C. No specific manufacturing requests are being made at this time. Such requests would be made to the Board on a case-by-case basis.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is September 17, 2001. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to October 2, 2001).

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce, International Trade Administration, Export Assistance Center, 2345 Grand Boulevard, Suite 650, Kansas City, MO 64108

Office of the Executive Secretary, Foreign-Trade Zones Board, Room 4008, U.S. Department of Commerce, 14th & Pennsylvania Avenue, NW., Washington, DC 20230

Dated: July 9, 2001.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 01–18120 Filed 7–18–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–827]

Certain Cased Pencils From the People's Republic of China; Final Results and Partial Rescission of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results and partial rescission of antidumping duty administrative review.

SUMMARY: On January 9, 2001, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on certain cased pencils (pencils) from the People's Republic of China (PRC). *See Notice of Preliminary Results of Antidumping Duty Administrative Review: Certain Cased Pencils from the People's Republic of China,* 66 FR 1638 (January 9, 2001). This review covers a manufacturer/exporter of the subject merchandise (China First Pencil Co., Ltd.) and a manufacturer of the subject merchandise (Three Star Stationary Co., Ltd.). In its March 16, 2000, response to the Department's questionnaire, Three Star stated that it did not export pencils to the United States during the POR. In addition, as described in the preliminary results, we rescinded the review for one respondent and did not receive questionnaire responses from 30 named respondents. The period of review (POR) is December 1, 1998, through November 30, 1999.

Based on our analysis of the comments received, our final results remain unchanged from the preliminary results.

EFFECTIVE DATE: July 19, 2001.

FOR FURTHER INFORMATION CONTACT: Paul Stolz, Office of AD/CVD Enforcement, Office 4, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone (202) 482–4474.

SUPPLEMENTARY INFORMATION:

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless

otherwise indicated, all citations to the Department's regulations are to 19 CFR part 351 (2000).

Background

On January 9, 2001, the Department published in the **Federal Register** the preliminary results of the administrative review of the antidumping duty order on pencils from the PRC. *See Notice of Preliminary Results and Rescission in Part of Antidumping Duty Administrative Review of Certain Cased Pencils from the People's Republic of China, 66 FR 1638 (January 9, 2001).*

China First Pencil Co., Ltd. (CFP) and Three Star Stationary Co., Ltd. (Three Star) (respondents), and the Pencil Section of the Writing Instrument Manufacturers Association, Sanford Corporation, Dixon-Ticonderoga Corporation, Tennessee Pencil Company, Musgrave Pencil Company, Moon Products, Inc., General Pencil Company, and Aakron Rule, Inc., (petitioners) filed case briefs on March 2, 2001 and rebuttal briefs on March 14, and 15, 2001 respectively. Rose Art Industries, Inc., a U.S. importer of the subject merchandise during the POR, filed a case brief on March 1, 2001.

The Department has conducted this administrative review in accordance with section 751 of the Act.

Scope of Review

Imports covered by this review are shipments of certain cased pencils of any shape or dimension which are writing and/or drawing instruments that feature cores of graphite or other materials, encased in wood and/or man-made materials, whether or not decorated and whether or not tipped (e.g., with erasers, etc.) in any fashion, and either sharpened or unsharpened. The pencils subject to this investigation are classified under subheading 9609.10.00 of the Harmonized Tariff Schedules of the United States (''HTSUS''). Specifically excluded from the scope of this investigation are mechanical pencils, cosmetic pencils, pens, non-cased crayons (wax), pastels, charcoals, and chalks.

Although the HTSUS subheading is provided for convenience and customs purposes our written description of the scope of the order is dispositive.

Final Partial Rescission

We are rescinding this review with respect to Three Star because the Department verified that Three Star did not export pencils to the United States during the POR.

Period of Review

The POR is December 1, 1998 to November 30, 1999.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this administrative review are addressed in the ''Issues and Decision Memorandum'' (''Decision Memorandum'') from Bernard T. Carreau, Deputy Assistant Secretary, Important Administration, to Faryar Shirzad, Assistant Secretary for Import Administration, dated concurrently with this notice, which is hereby adopted by this notice. A list of the issues which parties have raised and to which we have responded, all of which are in the Decision Memorandum, is attached to this notice as an Appendix. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum which is on file in the Central Record Unit, room B–099 of the main Department of Commerce building. In addition, a complete version of the Decision Memorandum can be accessed directly on the International Trade Administration's Web site at www.ia.ita.doc.gov. The paper copy and electronic version of the Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of comments received, we have made no changes to our preliminary results.

Final Results of Review

We determine that the following weighted-average percentage margin exists for the period December 1, 1998 through November 30, 1999:

Exporter/manufacturer	Margin (percent)
China First Pencil Co., Ltd	53.65
PRC Wide-Rate	53.65

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of this notice of final results of administrative review for all shipments of pencils from the PRC entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(1) of the Act: (1) The cash deposit rates for the reviewed companies will be the rates shown above; (2) for previously reviewed or investigated companies not listed above that have separate rates, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) the cash deposit rate for all other PRC exporters will continue to be 53.65 percent; and (4) the cash-deposit rate for non-PRC exporters will be the rate applicable to the PRC supplier of that exporter.

These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as the only reminder to parties subject to administrative protective orders (''APOs'') of their responsibility concerning the return or destruction of proprietary information disclosed under an APO in accordance with 19 CFR 351.305 or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this determination and notice in accordance with sections section 751(a)(1) and 771(i) of the Act.

Dated: July 9, 2001.

Faryar Shirzad,

Assistant Secretary for Import Administration.

Appendix—Issues in Decision Memorandum

Comments

1. Whether the Department Should Continue to Base the Dumping Margin on Total Adverse Facts Available.
2. Whether China First Pencil Co., Ltd. (CFP) and Three Star Stationery Industry Co., Ltd. (Three Star) Should be Treated as a Single Entity for Antidumping Purposes.
3. Whether to Calculate a Dumping Margin for Sales to the U.S. Importer, Rose Art Industries, Inc. (Rose Art), regardless of whether adverse facts available are applied to all other sales.
4. Whether to Use American Basswood Prices or Indonesian Slat Prices to Value Chinese Lindenwood.
5. Whether to Use Sales Commissions and Bank Charges in Calculating a Dumping Margin.
6. Whether to Use Indonesian Surrogate Values to Calculate the Dumping Margin.

[FR Doc. 01–18119 Filed 7–18–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–504]

Porcelain-on-Steel Cookware From Mexico: Notice of Extension of Time Limit for Preliminary Results in Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: July 19, 2001.

FOR FURTHER INFORMATION CONTACT: Rebecca Trainor at (202) 482–4007, or Katherine Johnson at (202) 482–4929, Office 2, AD/CVD Enforcement Group I, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC, 20230.

SUMMARY: The Department of Commerce is extending the time limit for the preliminary results of the fourteenth administrative review of the antidumping duty order on porcelain-on-steel cookware from Mexico, which covers the period December 1, 1999, through November 30, 2000.

Applicable Statute: Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department of Commerce (the Department) regulations are to 19 C.F.R. Part 351 (April 2000).

SUPPLEMENTARY INFORMATION: Pursuant to section 751(a)(3)(A) of the Act, the Department shall make a preliminary determination in an administrative review of an antidumping duty order within 245 days after the last day of the anniversary month of the date of publication of the order. The Act further provides, however, that the Department may extend that 245-day period to 365 days if it determines it is not practicable to complete the review within the foregoing time period. The Department finds that it is not practicable to complete the preliminary results in this fourteenth administrative review of porcelain-on-steel cookware from Mexico within this time limit because we must request additional information and clarification of submitted data from the respondents.

Therefore, in accordance with section 751(a)(3)(A) of the Act, the Department is extending the time for completion of the preliminary results of this review until November 5, 2001.

Dated: July 12, 2001.

Richard W. Moreland,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 01–18121 Filed 7–18–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–337–804]

Certain Preserved Mushrooms from Chile: Notice of Extension of Time Limit for Preliminary Results in Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: July 19, 2001.

FOR FURTHER INFORMATION CONTACT: Sophie Castro at (202) 482–0588, or David J. Goldberger at (202) 482–4136, Office 2, AD/CVD Enforcement Group I, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC, 20230.

SUMMARY: The Department of Commerce is extending the time limit for the preliminary results of the administrative review of the antidumping duty order on certain preserved mushrooms from Chile, which covers the period December 1, 1999, through November 30, 2000.

APPLICABLE STATUTE: Unless otherwise indicated, all citations to th Tariff Act of 1930, as amended (the Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department of Commerce (the Department) regulations are to 19 CFR Part 351 (April 2000).

SUPPLEMENTARY INFORMATION: Pursuant to section 751(a)(3)(A) of the Act, the Department shall make a preliminary determination in an administrative review of an antidumping duty order within 245 days after the last day of the anniversary month of the date of publication of the order. The Act further provides, however, that the Department may extend that 245-day period to 365 days if it determines it is not practicable to complete the review within the foregoing time period. The Department finds that it is not practicable to complete the preliminary results in this administrative review of certain preserved mushrooms from Chile within this time limit because we must request additional information and clarifications of submitted data from the respondent as well as deal with administrative resource constraints.

Therefore, in accordance with section 751(a)(3)(A) of the Act, the Department is extending the time for completion of the preliminary results of this review until November 15, 2001.

Dated: July 13, 2001.

Richard W. Moreland,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 01–18122 Filed 7–18–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–813, A–560–802, A–570–851]

Certain Preserved Mushrooms From India, Indonesia, and the People's Republic of China: Notice of Extension of Time Limit for Preliminary Results in Antidumping Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce

EFFECTIVE DATE: July 19, 2001.

FOR FURTHER INFORMATION CONTACT: Kate Johnson at (202) 482–4929, or David J. Goldberger at (202) 482–4136, Office 2, AD/CVD Enforcement Group I, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC, 20230.

SUMMARY: The Department of Commerce is extending the time limit for the preliminary results of the administrative reviews of the antidumping duty order on certain preserved mushrooms from India, Indonesia, and the People's Republic of China, which cover the period February 1, 2000, through January 31, 2001.

Applicable Statute: Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department of Commerce (the Department) regulations are to 19 CFR Part 351 (April 2000).

SUPPLEMENTARY INFORMATION: Pursuant to section 751(a)(3)(A) of the Act, the Department shall make a preliminary

determination in an administrative review of an antidumping duty order within 245 days after the last day of the anniversary month of the date of publication of the order. The Act further provides, however, that the Department may extend that 245-day period to 365 days if it determines it is not practicable to complete the review within the foregoing time period. The Department finds that it is not practicable to complete the preliminary results in these administrative reviews of certain preserved mushrooms from India, Indonesia, and the People's Republic of China within this time limit because we must request additional information and clarifications of submitted data from the respondents as well as deal with administrative resource constraints.

Therefore, in accordance with section 751(a)(3)(A) of the Act, the Department is extending the time for completion of the preliminary results of these reviews until February 28, 2002.

Dated: July 13, 2001.

Richard W. Moreland,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 01–18123 Filed 7–18–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–501]

Certain Welded Carbon Steel Pipe and Tube From Turkey: Notice of Recision of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of recision of antidumping duty administrative review.

EFFECTIVE DATE: July 19, 2001.

SUMMARY: On June 19, 2001, the Department of Commerce (the Department) published in the **Federal Register** (66 FR 32934) a notice announcing the initiation of an administrative review of the antidumping duty order on certain welded carbon steel pipe and tube from Turkey, covering the period May 1, 2000 through April 30, 2001, and one manufacturer/exporter of the subject merchandise, the Borusan Group. We are now rescinding this review as a result of the respondent's withdrawal of its request for an administrative review.

FOR FURTHER INFORMATION CONTACT: Charles Riggle at (202) 482–0650 or David Layton at (202) 482–0371, Import Administration, Room 1870, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Applicable Statute And Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to Department of Commerce (the Department) regulations refer to the regulations codified at 19 CFR part 351 (April 2000).

Background

On May 31, 2001, the Borusan Group, in accordance with 19 CFR 351.213(b), requested an administrative review of the antidumping duty order on certain welded carbon steel pipe and tube from Turkey. On June 19, 2001, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review of this order for the period May 1, 2000 through April 30, 2001 (66 FR 32934, June 19, 2001). On June 20, 2001, the Borusan Group withdrew its request for this review.

Recision of Review

The Department's regulations at 19 CFR 351.213(d)(1) provide that the Department will rescind an administrative review if the party that requested the review withdraws its request for review within 90 days of the date of publication of the notice of initiation of the requested review, or withdraws its request at a later date if the Department determines that it is reasonable to extend the time limit for withdrawing the request. The Borusan Group withdrew its request for review within the 90-day period. Accordingly, this review is rescinded. This determination is issued and published in accordance with section 751 of the Act (19 U.S.C. 1675) and 19 CFR 351.213(d)(4).

July 12, 2001.

Bernard T. Carreau,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 01–18124 Filed 7–18–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 062701B]

Marine Mammals: Environmental Assessment on Allocating Gray Whales to the Makah Tribe for the years 2001 and 2002

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

ACTION: Notice of availability.

SUMMARY: NMFS announces the availability of an Environmental Assessment (EA) that examines the environmental consequences of issuing the International Whaling Commission (IWC) quota for gray whales to the Makah Tribe for the years 2001 and 2002. NMFS has identified a preferred alternative in the EA that will grant the Makah Tribe the IWC quota of five whales per year with restrictions that would allow a limited hunt on the gray whale summer feeding aggregation.

ADDRESSES: Copies of the EA may be obtained over the Internet at http://www.nmfs.noaa.gov/prot—res/prot—res.html under ''New Arrivals.'' Copies of the EA may also be requested by writing to Gale Heim, NOAA/NMFS, Office of Protected Resources, 13th Floor, 1315 East-West Hwy, Silver Spring, MD 20910. Mark the outside of the envelope with ''Request for Makah EA.'' Copies of the EA may also be obtained by contacting Gale Heim at 301/713–2322.

FOR FURTHER INFORMATION CONTACT: Cathy Campbell or Chris Yates, 301-713–2322.

SUPPLEMENTARY INFORMATION: Prior to the 1997 Annual International Whaling Commission (IWC) Meeting, NMFS formally analyzed the environmental impacts of a decision to support or not support whaling, and to determine whether an annual subsistence quota of up to five Eastern Pacific gray whales would significantly affect the quality of the human environment. A draft EA was distributed for public comment on August 22, 1997. After reviewing and addressing the comments received, NMFS issued a final EA and Finding of No Significant Impact on October 17, 1997.

At its 1997 annual meeting, the IWC approved a quota of 620 gray whales for an aboriginal subsistence harvest during the years 1998 through 2002. The basis for the quota was a joint request by the Russian Federation (for a total of 600

whales) and the United States (for a total of 20 whales). In 1998 and 1999, NOAA granted an allocation of up to five whales a year to the Makah Indian Tribe, whose subsistence and ceremonial needs had been the foundation of the U.S. request to the IWC.

U.S. Congressman Jack Metcalf, Breach Marine Protection, and several other plaintiffs brought a lawsuit, *Metcalf* v. *Daley*, in October 1997, alleging that the U.S. Government had violated the National Environmental Policy Act (NEPA), the Whaling Convention Act, and other statutes. In September 1998, the U.S. District Court for the Western District of Washington ruled in favor of the U.S. Government on all issues.

On June 9, 2000, the Ninth Circuit Court of Appeals overturned one aspect of that decision, ruling that the 1997 EA should have been completed before the U.S. and the Makah Tribe entered into a cooperative agreement. That agreement had provided that, if the Tribe prepared an adequate needs statement documenting a cultural and subsistence need to harvest gray whales, NOAA would request a quota of gray whales from the IWC. Two judges on a three-judge panel held that the timing of the EA, which was completed after the 1996 agreement was signed and before the 1997 annual meeting of the IWC, may have predisposed the preparers to find that the whaling proposal would not significantly affect the environment. The Court ordered NOAA to set aside that finding and comply with NEPA under circumstances that would ensure an objective evaluation of the environmental consequences of the gray whale harvest.

Following the Court action, NOAA rescinded its cooperative agreement with the Makah Tribe on August 11, 2000. NOAA subsequently set the gray whale quota for 2000 (65 FR 75186, December 1, 2000) and 2001 (65 FR 14862, March 14, 2001) at zero, pending completion of its NEPA analysis.

NEPA requires that Federal agencies conduct an environmental analysis of their actions to determine if the actions may affect the environment. Accordingly, NMFS prepared a draft EA, published on January 12, 2001, conducted a public hearing in Seattle, WA on February 1, 2001, and held a 30–day public comment period to allow for public input on the Draft EA. This final EA explores the environmental consequences of four alternatives: (1) grant Makah Tribe the IWC quota with restrictions that allow a limited hunt on the pacific coast feeding aggregation; (2) grant Makah Tribe the IWC quota with restrictions to target hunt on migrating whales (similar to the 1999 regime); (3) grant Makah Tribe the IWC quota without time-area restrictions; and (4) (no action) - do not grant Makah Tribe the IWC quota. NMFS has identified the preferred alternative as alternative 1, which will grant the Makah Tribe the IWC quota of five whales per year with restrictions that would allow a limited hunt on the gray whale summer feeding aggregation.

This EA was prepared in accordance with NEPA and implementing regulations at 40 CFR parts 1500 through 1508 and NOAA guidelines concerning implementation of NEPA found in NOAA Administrative Order 216–6.

Dated: July 13, 2001.

Don Knowles,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 01–18005 Filed 7–16–01; 10:34 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 070201B]

Marine Mammals; File No. 116–1477

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

ACTION: Issuance of permit amendment.

SUMMARY: Notice is hereby given that SeaWorld, Inc., 7007 Sea World Drive, Orlando, FL 32821–8097 (Principal Investigator: Dudley Wigdahl, SeaWorld of Texas) has been issued an amendment to scientific research and enhancement Permit No. 116–1477 to take Hawaiian monk seals, *Monachus schauinslandi*, for scientific research purposes.

ADDRESSES: The permit amendment and related documents are available for review upon written request or by appointment in the following office(s): see **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Amy Sloan or Ruth Johnson, 301/713–2289.

SUPPLEMENTARY INFORMATION: On May 21, 2001, notice was published in the **Federal Register** (66 FR 27941) that a request for an amendment to scientific research and enhancement Permit No. 116–1477, to take Hawaiian monk seals, *Monachus schauinslandi*, had been submitted by the above-named organization. The requested amendment has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered fish and wildlife (50 CFR parts 217–227).

Issuance of this permit amendment, as required by the ESA, was based on a finding that such permit amendment (1) was applied for in good faith, (2) will not operate to the disadvantage of the endangered species which is the subject of this permit, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

The permit amendment and related documents are available for review in the following office(s):

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 713–2289; fax (301) 713–0376;

Regional Administrator, Southwest Region, NMFS, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802–4213; phone (562) 980–4001; fax (562) 980–4018;

Regional Administrator, Southeast Region, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702–2432; phone (727) 570–5301; fax (727) 570–5320; and

Protected Species Program Manager, Pacific Islands Area Office, 1601 Kapiolani Blvd., Room 1110, Honolulu, HI 96814–4700; phone (808) 973–2935; fax (808) 973–2941.

Dated: July 13, 2001.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 01–18102 Filed 7–18–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 01–16]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36 (b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSCA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 01–16 with attached transmittal, policy justification, and Sensitivity of Technology.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–08–M

DEFENSE SECURITY COOPERATION AGENCY

WASHINGTON, DC 20301-2800

26 JUN 2001
In reply refer to:
I-01/006649

The Honorable J. Dennis Hastert
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 01-16 and under separate cover the classified offset certificate thereto. This Transmittal concerns the Department of the Army's proposed Letter(s) of Offer and Acceptance (LOA) to the Republic of Korea for defense articles and service estimated to cost $2.4 billion. Soon after this letter is delivered to your office, we plan to notify the news media of the unclassified portion of this Transmittal.

Reporting of Offset Agreements in accordance with Section 36(b)(1)(C) of the Arms Export Control Act (AECA), as amended, requires a description of any offset agreement with respect to this proposed sale. Section 36(g) of the AECA, as amended, provides that reported information related to offset agreements be treated as confidential information in accordance with section 12(c) of the Export Administration Act of 1979 (50 U.S.C. App. 2411(c)). Information about offsets for this proposed sale are described in the enclosed confidential attachment.

Sincerely,

A.R. KELTZ
DEPUTY DIRECTOR

Attachment
As stated

Separate Cover:
Offset certificate

Same ltr to: House Committee on International Relations
Senate Committee on Appropriations
Senate Committee on Foreign Relations
House Committee on Armed Services
Senate Committee on Armed Services
House Committee on Appropriations

Transmittal No. 01-16

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) **Prospective Purchaser: Republic of Korea**

(ii) **Total Estimated Value:**

Major Defense Equipment*	$1.9 billion
Other	$ .5 billion
TOTAL	$2.4 billion

(iii) **Description and Quantity or Quantities of Articles or Services under Consideration for Purchase: Thirty-six AH-64D Apache attack helicopters; 14 spare T-700-GE-701C engines; 85 M299 HELLFIRE launchers; 410 AGM-114L1 and 576 AGM-114K1 HELLFIRE II laser guided missiles; 40 AGM-114 training and 40 AGM-114 dummy missiles; 310 STINGER Block 1 missiles; two spare Modernized Targeting Acquisition and Designation Systems; 16 AN/APG-78 Longbow Fire Control Radar; 39 AN/ARC-210 SINCGARS radios with HAVE QUICK; 23,904 2.75 rockets, M130 chaff dispensers; spare and repair parts, communications equipment, support equipment, simulators, quality assurance teams, tools and test sets, chaff dispensers, Integrated Helmet and Display Sight Systems, 30mm cartridges, electronic equipment, test facility spares, publications, personnel training and training equipment, U.S. Government and contractor technical support and other related elements of logistics support.**

(iv) **Military Department: Army (YVS, YVT, OFQ, KZJ, KWW, and BQS)**

(v) **Prior Related Cases, if any: FMS case JAJ - $404 million - Cancelled**

(vi) **Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None**

(vii) **Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached**

(viii) **Date Report Delivered to Congress: 26 JUN 2001**

*** as defined in Section 47(6) of the Arms Export Control Act.**

POLICY JUSTIFICATION

Republic of Korea - AH-64D Apache Helicopters

The Republic of Korea Government (ROKG) has requested the possible sale of 36 AH-64D Apache attack helicopters; 14 spare T-700-GE -701C engines; 85 M299 HELLFIRE launchers; 410 AGM-114L1 and 576 AGM-114K1 HELLFIRE II laser guided missiles; 40 AGM-114 training and 40 AGM-114 dummy missiles; 310 STINGER Block 1 missiles; two spare Modernized Targeting Acquisition and Designation Systems; 16 AN/APG-78 Longbow Fire Control Radar; 39 AN/ARC-210 SINCGARS radios with HAVE QUICK; 23,904 2.75 rockets, M130 chaff dispensers; spare and repair parts, communications equipment, support equipment, simulators, quality assurance teams, tools and test sets, chaff dispensers, Integrated Helmet and Display Sight Systems, 30mm cartridges, electronic equipment, test facility spares, publications, personnel training and training equipment, U.S. Government and contractor technical support and other related elements of logistics support. The estimated cost is $2.4 billion.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country which has been and continues to be an important force for political stability and economic progress in Northeast Asia.

Korea desires these articles to fulfill their strategic commitments for self-defense and self-reliance. The proposed sale will upgrade its anti-armor day/night missile capability, provide for the defense of vital installations and provide close air support for the military ground forces. Korea will have no difficulty absorbing these helicopters into its armed forces.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The principal contractors will be Boeing Company in Mesa, Arizona; Lockheed Martin Electronics and Missiles in Orlando, Florida; Lockheed Martin Federal Systems in Owego, New York; General Electric in Lynn, Massachusetts; and Longbow LLC in Orlando, Florida. One or more proposed offset agreements may be related to this proposed sale.

Implementation of this sale will require the assignment of several U.S. Government Quality Assurance Teams to Korea for one month to assist in the delivery and deployment of the missiles. There will be up to 15 U.S. Government representatives for two-week intervals twice annually to participate in program management and technical reviews. Five contractor representatives will serve as technical representatives for a period of three years following initial deployment. Contractor representatives representing varying technical skills and disciplines will be required to provide in-country support for an extended period of time. The specific requirements for this support will be established during program definition between representatives of the United States Government and the purchaser.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

The ROKG is also considering a competing bid for 36 Super Cobra helicopters.

Transmittal No. 01-16

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act (U)

Classified Annex
Item No. vi

(vi) Sensitivity of Technology:

1. The AH-64D Apache Attack Helicopter includes the following classified or sensitive components:

a. AN/APG-78 Longbow Fire Control Radar (FCR) is an active fire control radar system providing detection, location, classification and prioritization of targets to be prosecuted by the Longbow HELLFIRE Modular Missile System or handed over to other on-board sensor systems. This enables the Apache helicopter to detect and fire upon targets in visual conditions that preclude the use of visual or infrared imaging systems. Hardware is Unclassified, releasable technical manuals for operation and organic level maintenance are Unclassified. The data, including operational software, proposed for release will not, in itself, facilitate reverse engineering.

b. AN/APR-48A Radar Frequency Interferometer (RFI) is part of the AN/APG-78 FCR. It passively detects, locates in azimuth, and identifies radar emitters and sends the emitter identification and location to either the FCR or to the Apache Weapons Processor for display to the aircrew. Emitter information can also be used to cue the FCR, as well as for making decisions on FCR target prioritization. Hardware is classified Confidential when the User Data Module (UDM) is attached to the RFI Processor Assembly, Unclassified when the UDM is absent. Releasable technical manuals for operation and organic level maintenance are Unclassified. The data, including operational software, proposed for release will not facilitate reverse engineering.

c. The Modernized Target Acquisition and Designation Sight/Pilot Night Vision Sensor (TADS/PNVS) with Optical Improvements (OIP) system provides day, night, limited adverse weather target information, as well as night navigation capabilities. The PNVS provides thermal imaging that permits nap-of-the-earth flight to, from, and within the battle area, while TADS provides the co-pilot gunner with search, detection, recognition, and designation by means of Direct View Optics (DVO), television, and Forward Looking Infrared (FLIR) sighting systems that may be used singularly or in combinations. Hardware is Unclassified. Technical manuals for authorized maintenance levels are Unclassified. Reverse engineering is not a major concern.

d. The AGM-114K1 and AGM-114L1 HELLFIRE air-to-surface laser missile hardware and documentation are unclassified. Missile performance parameters and characteristics, including susceptibility to countermeasures, are classified up to Secret and considered very sensitive. Missile hardware is considered sensitive and knowledge of the warhead timing mechanism would be useful in development of countermeasures. Technology contained within the missile is sensitive and Unclassified. The sensitivity of the system is primarily in the software programs which enable the missile to operate in a countermeasures environment. Training, maintenance, operations and related documentation are unclassified and not considered sensitive.

e. The Stinger Block I missile, Platform Launch, was specifically designed to counter the threat of high speed, maneuvering aircraft, advanced helicopters and UAVs/RVS.

The Stinger Weapon System affords a quick reaction, fire and forget capability not available with conventional defense systems. Stinger utilizes a passive IR/UV seeker and proportional navigational guidance, which allows the gunner to acquire, track and engage targets at any aspect. The materiel is classified Confidential and the releasable technical manuals are Restricted.

f. AN/ALQ-144A(V)3 Infrared Countermeasure Set - an active, continuous operating, omni-directional, electrically fired infrared jammer system designed to confuse or decoy threat IR missile systems, in conjunction with low reflective paint and engine suppressors. Hardware is classified Confidential. Technical manuals for authorized maintenance levels are classified Secret. Reverse engineering and development of counter-countermeasures are concerns if the hardware and releasable technical data were compromised.

g. M130 Chaff-flare Dispenser - a multi-purpose system which dispenses decoys to confuse threat radar and missile IR seekers. Radar cross section and frequency coverage are sensitive elements. Hardware is Unclassified. Technical publications for authorized maintenance levels are Unclassified. Aircraft optimization is the critical element; reverse engineering is not a major concern.

h. AN/APR-39A(V)4 Radar Signal Detecting Set - provides warning of a radar directed air defense threat to permit appropriate countermeasures. It is programmed with appropriate threat data. Hardware is classified Confidential. Technical manuals for the maintenance levels are classified Confidential. Technical performance data is classified Secret.

i. AN/ALQ-136(V)5 Radar Jammer Countermeasure Sets - an omni-directional radar jammer which provides protection against threat radar detecting devices. Equipment is programmed with appropriate threat data provided by purchasing country. Hardware is classified Confidential. Releasable technical manuals for the maintenance are classified Secret; releasable technical performance data is classified Secret. Technology involved in design, manufacturing and testing of the jammer is sensitive. Reverse engineering is a primary concern.

j. The Suite of Integrated Radio Frequency Countermeasures (SIRFC)/Suite of Integrated Infrared Countermeasures detects, identifies, and counters multiple, simultaneous, modern surface and airborne threat radars. SIRFC combines both radar warning and electronic countermeasures, and also provides full-threat radar warning frequency coverage including millimeter wave, while countering pulse, pulse doppler, continuous wave, and pulse compression threats.

k. AN/AVR-2A(V) Laser Warning Set is a passive laser warning system which receives, processes and displays threat information resulting from aircraft illumination by lasers, on the multi-functional display. The hardware is classified Confidential. Technical manuals for operation and maintenance levels are classified Secret.

l. AN/ARC-210 SINCGAR radio with HAVE QUICK II is a voice communications radio system and considered unclassified without HAVE QUICK II. HAVE QUICK II employs cryptographic technology which is classified Secret. Classified elements include operating characteristics, parameters, technical data, and keying material.

m. AN/APX-100 Identify Friend or Foe (IFF) Mode IV is Classified. Software is classified Confidential. Classified elements of the IFF system include operating characteristics, parameters, and technical data.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that Korea can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

[FR Doc. 01–18062 Filed 7–18–01; 8:45 am]
BILLING CODE 5001–08–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 01–17]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSCA/COMPT/RM, (703) 604–6575

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 01–17 with attached transmittal, policy justification, and Sensitivity of Technology.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–08–M

DEFENSE SECURITY COOPERATION AGENCY

WASHINGTON, DC 20301-2800

26 JUN 2001
In reply refer to:
I-01/006650

The Honorable J. Dennis Hastert
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 01-17 and under separate cover the classified offset certificate thereto. This Transmittal concerns the Department of the Navy's proposed Letter(s) of Offer and Acceptance (LOA) to the Republic of Korea for defense articles and service estimated to cost $1.6 billion. Soon after this letter is delivered to your office, we plan to notify the news media of the unclassified portion of this Transmittal.

Reporting of Offset Agreements in accordance with Section 36(b)(1)(C) of the Arms Export Control Act (AECA), as amended, requires a description of any offset agreement with respect to this proposed sale. Section 36(g) of the AECA, as amended, provides that reported information related to offset agreements be treated as confidential information in accordance with section 12(c) of the Export Administration Act of 1979 (50 U.S.C. App. 2411(c)). Information about offsets for this proposed sale are described in the enclosed confidential attachment.

Sincerely,

A.R. KELTZ
DEPUTY DIRECTOR

Attachment
As stated

Separate Cover:
Offset certificate

Same ltr to: House Committee on International Relations
Senate Committee on Appropriations
Senate Committee on Foreign Relations
House Committee on Armed Services
Senate Committee on Armed Services
House Committee on Appropriations

Transmittal No. 01-17

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) **Prospective Purchaser: Republic of Korea**

(ii) **Total Estimated Value:**

Major Defense Equipment*	$1.3 billion
Other	$ .3 billion
TOTAL	$1.6 billion

(iii) **Description and Quantity or Quantities of Articles or Services under Consideration for Purchase: Thirty-six AH-1Z Super Cobra helicopters, 14 spare T-700-GE-701C engines, 72 SIDEWINDER launchers, 85 M299 HELLFIRE launchers, 100 AIM-9X SIDEWINDER missiles, 576 AGM-114K1 HELLFIRE air-to-surface laser missiles, 40 AGM-114 training and 40 AGM-114 dummy missiles, 39 AN/ARC-210 SINCGARS radios with HAVE QUICK, 400 2.75 inch rockets, M130 chaff dispensers, 20mm cannons and rounds, rockets, spare and repair parts, communications equipment, support equipment, tools and test sets, supply support, publications, personnel training and training equipment, U.S. Government and contractor technical support and other related elements of logistics support.**

(iv) **Military Department: Navy (SDK) and Army (YWA)**

(v) **Prior Related Cases, if any: FMS case YII - $215 million - Cancelled**

(vi) **Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None**

(vii) **Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached**

(viii) **Date Report Delivered to Congress: 26 JUN 2001**

*** as defined in Section 47(6) of the Arms Export Control Act.**

POLICY JUSTIFICATION

Republic of Korea - AH-1 Cobra Attack Helicopters

The Republic of Korea Government (ROKG) has requested the possible sale of 36 AH-1Z Super Cobra helicopters, 14 spare T-700-GE-701C engines, 72 SIDEWINDER launchers, 85 M299 HELLFIRE launchers, 100 AIM-9X SIDEWINDER missiles, 576 AGM-114K1 HELLFIRE air-to-surface laser missiles, 40 AGM-114 training and 40 AGM-114 dummy missiles, 39 AN/ARC-210 SINCGARS radios with HAVE QUICK, 2.75 inch rockets, M130 chaff dispensers, 20mm cannons and rounds, rockets, spare and repair parts, communications equipment, support equipment, tools and test sets, supply support, publications, personnel training and training equipment, U.S. Government and contractor technical support and other related elements of logistics support. The estimated cost is $1.6 billion.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country which has been and continues to be an important force for political stability and economic progress in Northeast Asia.

Korea desires these articles to fulfill their strategic commitments for self-defense and self-reliance. The proposed sale will upgrade its anti-armor day/night missile capability, provide for the defense of vital installations and provide close air support for the military ground forces. Korea, which already has Cobra helicopters in its inventory, will have no difficulty absorbing these helicopters.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The principal contractors will be Bell Helicopter Textron, Incorporated in Hurst, Texas and Lockheed Martin in Orlando, Florida. One or more proposed offset agreements may be related to this proposed sale.

Implementation of this sale will require the assignment of three contractor technical representatives for three years during initial delivery and system check out of the Cobra helicopters.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

The ROKG is also considering a competing bid for 36 Apache attack helicopters.

Transmittal No. 01-17

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

Annex
Item No. vi

(vi) Sensitivity of Technology:

1. The AH-1Z Super Cobra helicopter is unclassified. Sensitive and/or classified (up to Secret) elements of the AH-1Z Super Cobra helicopter include hardware, accessories, components, and associated software for the following:

a. The external view of the AIM-9X SIDEWINDER missile is Unclassified and not sensitive. The AIM-9X features a high off bore-sight seeker, enhanced countermeasure rejection capability, improved acquisition range and the ability to integrate with aircraft sensors e.g. radar and Helmet Mounted Cueing System. The Seeker/Guidance and Control Section and the Target Detector are Confidential and contain sensitive state-of-the-art technology. Specifically, the infrared seeker sensitivity is a significant improvement over the previous AIM-9 variants.

b. Manuals and technical documents for the AIM-9X that are necessary or operational use and organizational maintenance have portions classified up to Secret. Performance and operating logic of the counter-countermeasures circuits are Secret. The hardware, software, and data identified are classified to protect vulnerabilities, design and performance parameters and similar critical information.

c. The AGM-114K1 HELLFIRE air-to-surface laser missile hardware and documentation are unclassified. Missile performance parameters and characteristics, including susceptibility to countermeasures, are classified up to Secret and considered very sensitive. Missile hardware is considered sensitive and knowledge of the warhead timing mechanism would be useful in development of countermeasures. Technology contained within the missile is sensitive and Unclassified. The sensitivity of the system is primarily in the software programs which enable the missile to operate in a countermeasures environment. Training, maintenance, operations and related documentation are unclassified and not considered sensitive.

d. AN/APX-100 Identify Friend or Foe (IFF) Mode IV is Classified. Software is classified Confidential. Classified elements of the IFF system include operating characteristics, parameters, and technical data.

e. M130 Chaff-flare Dispenser - a multi-purpose system which dispenses decoys to confuse threat radar and missile IR seekers. Radar cross section and frequency coverage are sensitive elements. Hardware is Unclassified. Technical publications for authorized maintenance levels are Unclassified. Aircraft optimization is the critical element; reverse engineering is not a major concern.

g. AN/ALQ-144A(V)3 Infrared Countermeasure Set - an active, continuous operating, omni-directional, electrically fired infrared jammer system designed to confuse or decoy threat IR missile systems, in conjunction with low reflective paint and engine suppressors. Hardware is classified Confidential. Technical manuals for authorized

maintenance levels are classified Secret. Reverse engineering and development of counter-countermeasures are concerns if the hardware and releasable technical data were compromised.

h. AN/APR-39A(V)4 Radar Signal Detecting Set - provides warning of a radar directed air defense threat to permit appropriate countermeasures. It is programmed with appropriate threat data. Hardware is classified Confidential. Technical manuals for the maintenance levels are classified Confidential. Technical performance data is classified Secret.

i. AN/AVR-2A(V) Laser Warning Set is a passive laser warning system which receives, processes and displays threat information resulting from aircraft illumination by lasers, on the multi-functional display. The hardware is classified Confidential. Technical manuals for operation and maintenance levels are classified Secret.

j. Target Sight System (TSS) provides targeting forward looking, visible light TV, and designating and ranging laser functions to provide strike targeting and terminal guidance for precision/non-precision weapons. The TSS provides stand-off weapons with the capability to attack land and ship targets under day/night or adverse weather conditions and provides both automatic and manual tracking of targets. The TSS is classified Secret due to vulnerability to countermeasures and counter-countermeasures capability.

k. AN/ARC-210 SINCGAR radio with HAVE QUICK II is a voice communications radio system and considered unclassified without HAVE QUICK II. HAVE QUICK II employs cryptographic technology which is classified Secret. Classified elements include operating characteristics, parameters, technical data, and keying material.

l. AAR-47(V)2 Missile Warning Receiver System is an aircraft mounted missile warning system. The system is passive and consists of four sensors (receiving antennas) and two other black box Weapons Replaceable Assemblies. The sensors are UV detectors: when a sensor detects a "missile launch", it sends the appropriate signal to the aircraft's central EW processor which then displays the missile alert to the aircrew and can, if selected, control the dispensing of the appropriate countermeasures. The four sensors can also detect laser energy.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that Korea can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

[FR Doc. 01–18063 Filed 7–18–01; 8:45 am]
BILLING CODE 5001–08–C

DEPARTMENT OF DEFENSE

Office of the Secretary

Strategic Environmental Research and Development Program, Scientific Advisory Board

ACTION: Notice.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee meeting:

Date of Meeting: August 8, 2001 from 0830 a.m to 1730 p.m. and August 9, 2001 from 0830 a.m to 1655 p.m.

Place: National Rural Electric Cooperative Association (NRECA), 4301 Wilson Boulevard, Conference Center Room 1, Arlington, VA 22203

Matters to be Considered: Research and Development proposals and continuing projects requesting Strategic Environmental Research and Development Program funds in excess of $1M will be reviewed.

This meeting is open to the public. Any interested person may attend, appear before, or file statements with the Scientific Advisory Board at the time and in the manner permitted by the Board.

For Further Information Contact: Ms. Veronica Rice, SERDP Program Office, 901 North Stuart Street, Suite 303, Arlington, VA or by telephone at (703) 696–2119.

Dated: July 12, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–18060 Filed 7–18–01; 8:45 am]

BILLING CODE 5001–08–M

DEPARTMENT OF DEFENSE

Department of the Air Force

Announcement of Interface Control Working Group (ICWG) Meeting for New L2 and L5 Signal Structures

AGENCY: Department of the Air Force, DoD.

ACTION: Notice, Interested parties may submit requests to attend and participate in this ICWG meeting.

SUMMARY: An interface control working group (ICWG) meeting for resolving issues related to ICD–GPS–705 and to ICD–GPS–200 changes is scheduled for July 26–27, 2001. ICD–GPS–705 describes the new civilian GPS signal (L5C) on the L5 frequency (1176.45 MHz). The changes for the civilian signal (L2C) on the L2 frequency (1227.60 MHz) are described in a draft proposed interface revision notice to ICD–GPS–200. Meeting location is to be determined (TBD) and will be based on the number of respondents. A further message to participants will be sent by July 19, 2001. A previous announcement requested the submission of comments regarding these signal descriptions. Comments are due by July 17, 2001. The first day of the meeting will be devoted to discussions of L5 issues. The agenda for the second day is TBD. A final agenda for both days will be sent by July 19, 2001. Submit suggested agenda items to cmdm@losangeles.af.mil. Please respond by July 17, 2001, and include the number of people that will be attending from your organization.

ADDRESSES: Submit meeting attendance requests to SMC/CZER, 2420 Vela Way, Suite 1467, El Segundo CA 90245–4659, ATTN: 1st Lt Reginald C. Victoria, or to ARINC, Inc., 2250 E. Imperial Highway, Suite 450, El Segundo CA 90245–3509, ATTN: Dr. R. Slattery. Submit e-mail requests to *cmdm@losangeles.af.mil,* or to *rhonda.slattery@arinc.com.* Comments may also be sent by fax to (310) 363–6387 or (310) 322–4474.

DATES: The suspense for meeting attendance requests is July 17, 2001. The memo distribution suspense for the meeting location memo is July 19, 2001. The date of the ICWG meeting is July 26–27, 2001.

FOR FURTHER INFORMATION CONTACT: Capt Eric Y. Moore, Configuration Management Processes Coordinator, (310) 363–5117, or 1st Lt Reginald C. Victoria, ICD–GPS–705 Point of Contact, (310) 363–6329, Dr. Rhonda Slattery, ARINC ICD–GPS–705 POC, (310) 726–1654. Addresses above.

SUPPLEMENTARY INFORMATION: The civilian and military communities use the Global Positioning System, which employs a constellation of 24 satellites to provide continuously transmitted signals to enable appropriately configured GPS user equipment to produce accurate position, navigation and time information.

Janet A. Long,

Air Force Federal Register Liaison Officer.

[FR Doc. 01–18077 Filed 7–18–01; 8:45 am]

BILLING CODE 5001–05–U

DEPARTMENT OF DEFENSE

Department of the Army

Revision of MTMC Freight Traffic Rules Publication No. 1B, Item 70, Entitled ''Capacity Loads''

AGENCY: Military Traffic Management Command, DOD.

ACTION: Notice.

SUMMARY: The Military Traffic Management Command (MTMC) as the Department of Defense (DOD) Traffic Manager for surface and surface inter-modal traffic management services (DTR vol. 2, pgs 201–13 through 201–14) hereby modifies the text of the existing item entitled ''Capacity Load'' in the MFTRP 1B item 70. The purpose of this change is to streamline and clarify the application of capacity load by motor carriers doing business with DOD shippers.

DATES: This change is effective September 1, 2001.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Lord at (757) 878–8547 or via e-mail at *lords@mtmc.army.mil.*

SUPPLEMENTARY INFORMATION: A notice proposing this change was published in the **Federal Register**, 66 FR 14359, Monday, March 12, 2001. In response to this notice, a total of three (3) comments were received. A summary of the comments and MTMC's responses are as follows:

Comment one (1): Elimination of Double-Type van trailers will prevent carriers' from receiving sufficient revenue when hauling light and bulky freight.

Response one (1): MTMC recognizes the important role that less-than-truckload (LTL) carriers play in the Defense Transportation System (DTS) and in no-way intends to harm that section of the industry. It must also be recognized that equipment AV1 and AY1 also know as ''Pups'' are not the conveyance of choice for shipments which are light and bulky. Larger equipment is required and should be requested. MTMC will therefore add paragraph 5b to item 70 which states, ''This rule also does not apply to charges based on rate qualifiers: AA1, AF1, AY1, AY2, AV1, AZ1, and AG4. However, when a consignor inadvertently tenders a shipment that exceeds 20,000 pounds or 28 linear feet of loading space on the above listed equipment, the carrier is entitled to bill the consignor using a minimum weight of 20,000 pounds or actual weight whichever is greater. The carrier may not substitute a vehicle that is smaller than what is requested by the consignor.''

Comment two (2): Commenter took exception to proposed paragraph 1. Where it states, ''In order for a shipment to be classified as a capacity load, the BoL must be annotated as ''Vehicle Fully Loaded'' with an authorized person (e.g., Transportation Officer, Transportation Assistant, etc.), having full knowledge of the shipment, initialing the BoL at the time of pick-up.''

Response two (2): MTMC has determined that it is in the best interest of the Government for only authorized personnel with knowledge of the shipment to adjust costing factors on a Bill of Lading (BoL). MTMC also recognizes that contractor personnel operate many facilities. Therefore, paragraph 1 of the item has been altered to state, ''In order for a shipment to be classified as a capacity load, the BoL must be annotated as ''Vehicle Fully Loaded'' with an authorized Government representative (e.g. Transportation Officer, Transportation Assistant, authorized contractor personnel, etc.), having full knowledge of the shipment, initialing the BoL at the time of pick-up.''

Comment three (3): The removal of wording from paragraph 1(B) ''because of the necessity for segregation or separation from other freight requires the entire vehicle'' creates a situation where carriers will lose revenue from loss of loading space.

Response three (3): After careful review, MTMC concurs with comment and the paragraph in question has been restored to original text.

Comment four (4): Addressed paragraph 3 ''it is the carrier's responsibility to efficiently load (e.g.

stacking items when appropriate, etc.) on the vehicle provided.'' Commenter asserted the proposed wording is open to interpretation and dispute and provides no true guidance.

Response four (4): Most DoD facilities are shipper load, but ultimately it is the carriers' responsibility to ensure the safe and efficient loading of the freight. The placement of this text in the Capacity Load rule addresses an infrequent practice of spreading the freight throughout the vehicle in order to qualify for a truckload rate.

The complete text of Item 70 will read as follows:

Capacity Load (Item 70):

1. A shipment is considered a *capacity* load (also known as ''*loaded to full visible capacity*'', ''*loaded to capacity*'') when it occupies the full visible capacity of a vehicle, as defined in paragraph 2 below. In order for a shipment to be classified as a capacity load, the BoL must be annotated as ''Vehicle Fully Loaded'' with an authorized Government representative (e.g., Transportation Officer, Transportation Assistant, authorized contractor personnel, etc.), having full knowledge of the shipment, initialing the BoL at the time of pick-up. Shipments are to be considered as capacity loads if:

a. The shipment occupies 90% of the cargo carrying capacity of the vehicle; or

b. Because of unusual shape or dimensions, or because of the necessity for segregation or separation from other freight, requires the entire vehicle: or

c. Fills a vehicle so that no additional article, equivalent in size to the largest piece tendered, can be loaded in or on the vehicle.

2. For the purposes of this ITEM, a ''vehicle'' is defined as:

a. A van trailer of not less than forty (40) feet in length and not less than 2,700 cubic feet capacity; or

b. An open top trailer of not less than forty (40) feet in length, or

c. A flatbed trailer of not less than forty (40) feet in length.

3. Under no circumstances shall a carrier bill a shipment as a capacity load if the equipment requested by the shipper, or provided by the carrier, fails to meet the definitions shown in paragraph 2 above. Additionally, it is the carrier's responsibility to ensure the safe and efficient loading of freight (e.g., stacking items when appropriate, etc.) on the vehicle provided.

4. a.The charge for each vehicle loaded to full visible capacity will be based on either the truckload charge, when Rate Qualifiers PL and PM are used; or the highest truckload minimum weight (or actual weight if in excess of the applicable minimum weight) and accompanying truckload rate applicable to the equipment ordered and loaded. Under no circumstances will a line-haul charge be calculated using a minimum weight greater than 45,000 lbs.

b. Shipments rated using line-haul charges based upon Rate Qualifier PQ (MTMC Class 100 Rates) will be calculated using the greater of the actual weight or 40,000 lbs.

Note: All over-dimensional or overweight shipments, as defined in ITEM *415* and ITEM *416,* respectively, are subject to the Spot Bid provisions of ITEM *18,* paragraph 7.

5. a. This rule does not apply to charges based on rate qualifiers: DH (Per CWT per Dromedary Shipment), DL (Per Dromedary Service Shipment), DZ (Per CWT Per Mile Per Dromedary Shipment), PG (Per Gallon), ST (Per Short Ton), MV (Per Mile Per Vehicle Used), PV (Per Vehicle), and PY (Per Gallon Per Mile). Additionally, this rule does not apply to equipment types: AD (Dromedary Box without mechanical restraining devices), AD6 (Dromedary Box with mechanical restraining devices), A10 (410 Dromedary Box without mechanical restraining devices), A16 (410 Dromedary Box with mechanical restraining devices), or A20 (Motor Vehicle Transport Trailer). In the event that additional dromedary rate qualifiers and/or dromedary equipment codes are developed, this rule shall not apply to them as well.

b. This rule also does not apply to charges based on equipment types: AA1, AF1, AY1, AY2, AV1, AZ1, and AG4. However, when a consignor inadvertently tenders a shipment that exceeds 20,000 pounds or 28 linear feet of loading space on the above listed equipment, the carrier is entitled to bill the consignor using a minimum weight of 20,000 pounds or actual weight whichever is greater. The carrier may not substitute a vehicle that is smaller than what is requested by the consignor.

6. The application of capacity load will in no way restrict the carrier from adding additional freight to the equipment and should not be interpreted as a request for Exclusive Use of the vehicle.

Regulatory Flexibility Act: This change is not considered rule making within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612. Paperwork Reduction Act: The Paperwork Reduction Act, 44 U.S.C. 3051 *et seq.*, does not apply because no information collection requirement or recordkeeping responsibilities are imposed on offerors, contractors, or members of the public.

Edward Brown, Jr.,

Assistant Deputy Chief of Staff, CONUS Traffic Management.

[FR Doc. 01–18014 Filed 7–18–01; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of the Army

Availability for Non-Exclusive, Exclusive, or Partially Exclusive Licensing of U.S. Patent Application Concerning Anthrax Vaccines

AGENCY: U.S. Army Medical Research and Material Command, DoD.

ACTION: Notice.

SUMMARY: In accordance with 37 CFR 404.6, announcement is made of the availability for licensing of U.S. Patent Application Serial No. 09/350,729 entitled ''Anthrax Vaccines'' and filed July 9, 1999. Foreign rights are also available (PCT/US99/15568). This patent application has been assigned to the United States Government as represented by the Secretary of the Army.

ADDRESSES: Commander, U.S. Army Medical Research and Material Command, ATTN: Command Judge Advocate, MCMR–JA, 504 Scott Street, Fort Detrick, Frederick, Maryland 21702–5012.

FOR FURTHER INFORMATION CONTACT: For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619–7808. For licensing issues, Dr. Paul Mele, Office of Research & Technology Assessment, (301) 619–6664. Both at telefax (301) 619–5034.

SUPPLEMENTARY INFORMATION: Using the nontoxic PA protein from B. anthracis, a method and composition for use in inducing an immune response which is protective against anthrax in subjects is described.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–18011 Filed 7–18–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Availability for Non-Exlcusive, Exclusive, or Partially Exclusive Licensing of U.S. Patent Concerning Differentially Acting OP Detoxifying Sponges

AGENCY: U.S. Army Medical Research and Material Command, DoD.

ACTION: Notice.

SUMMARY: In accordance with 37 CFR 404.6, announcement is made of the availability for licensing of U.S. Patent Application Serial No. 09/559,396 entitled ''Differentially Acting OP Detoxifying Sponges'' filed April 26, 2000. Foreign rights are also available (PCT/US00/11070). This patent application has been assigned to the United States Government as represented by the Secretary of the Army.

ADDRESSES: Commander, U.S. Army Medical Research and Material Command, ATTN: Command Judge Advocate, MCMR–JA, 504 Scott Street, Fort Detrick, Maryland 21702–5012.

FOR FURTHER INFORMATION CONTACT: For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619–7808. For licensing issues, Dr. Paul Mele, Office of Research & Technology Assessment, (301) 619–6664. Both at telefax (301) 619–5034.

SUPPLEMENTARY INFORMATION: A material comprising a porous support and a plurality of enzymes for the removal, decontamination or neutralization of hazardous chemicals such as OP compounds is disclosed. The material may be used on a variety of surfaces, including natural, synthetic, and biological surfaces such as skin and other delicate membranes. Also disclosed is a process of making the material, kits and various methods of reactivation devices for reactivating the enzymatic activity of the material.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–18006 Filed 7–18–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Availability for Non-Exclusive, Exclusive, or Partially Exclusive Licensing of U.S. Patent Application Concerning Immobilized Enzymes as Biosensors for Chemical Toxins

AGENCY: U.S. Army Medical Research and Materiel Command, DoD.

ACTION: Notice.

SUMMARY: In accordance with 37 CFR 404.6, announcement is made of the availability for licensing of U.S. Patent Application No. 09/558,511 entitled ''Immobilized Enzymes as Biosensors for Chemical Toxins'' filed April 26, 2000. This patent has been assigned to the United States Government as represented by the Secretary of the Army.

ADDRESSES: Commander, U.S. Army Medical Research and Materiel Command, ATTN: Command Judge Advocate, MCMR–JA, 504 Scott Street, Fort Detrick, Frederick, Maryland 21702–5012.

FOR FURTHER INFORMATION CONTACT: For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619–7808. For licensing issues, Dr. Paul Mele, Office of Research & Technology Assessment, (301) 619–6664. Both at telefax (301) 619–5034.

SUPPLEMENTARY INFORMATION: Methods, compositions and materials useful in the detection of organophosphorus and organosulfur compounds are disclosed. In particular. biosensors wherein a porous or a non-porous support having any enzyme immobilized upon or within are disclosed. The biosensors exhibit enzymatic stability at extreme temperatures and/or denaturing conditions, and similar kinetic characteristics of the soluble form of the enzymes utilized. The enzyme does not leach from the porous or non-porous support and the material retains enzymatic activity after prolonged storage. Differential biosensors are also disclosed.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–18010 Filed 7–18–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Availability for Non-Exclusive, Exclusive, or Partially Exclusive Licensing of U.S. Patent Concerning Monoclonal Antibodies to Cholesteral and Methods

AGENCY: U.S. Army Medical Research and Materiel Command, DoD.

ACTION: Notice.

SUMMARY: In accordance with 37 CFR 404.6, announcement is made of the availability for licensing of U.S. Patent 4,885,256 entitled ''Monoclonal Antibodies to Cholesteral and Methods'' issued December 5, 1989. This patent has been assigned to the United States Government as represented by the Secretary of the Army.

ADDRESSES: Commander, U.S. Army Medical Research and Materiel Command, ATTN: Command Judge Advocate, MCMR–JA, 504 Scott Street, Fort Detrick, Frederick, Maryland 21702–5012.

FOR FURTHER INFORMATION CONTACT: For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619–7808. For licensing issues, Dr. Paul Mele, Office of Research & Technology Assessment, (301) 619–6664. Both at telefax (301) 619–5034.

SUPPLEMENTARY INFORMATION: Monoclonal antibodies which demonstrate specific reactivity to cholesterol and methods for the detection of high levels of cholesterol by contacting biological specimens containing cholesterol with the monoclonal antibodies and measuring the formation of antigen-antibody complexes by immunosorbent assay.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–18008 Filed 7–18–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Availability for Non-Exclusive, Exclusive, or Partially Exclusive Licensing of U.S. Patent Application Concerning a Rapid Method to Make OP Detoxifying Sponges Composed of Multiple Immobilized Enzymes of Cholinesterases and OP Hydrolases and Oximes as Reactivators

AGENCY: U.S. Army Medical Research and Materiel Command, DoD.

ACTION: Notice.

SUMMARY: In accordance with 37 CFR 404.6, announcement is made of the availability for licensing of U.S. Patent Application No. 09/558,512 entitled ''A Rapid Method to Make OP Detoxifying Sponges Composed of Multiple Immobilized Enzymes of Cholinesterases and OP Hydrolases and Oximes as Reactivators'' filed April 26, 2000. Foreign rights are also available (PCT/US00/11070). This patent has been assigned to the United States Government as represented by the Secretary of the Army.

ADDRESSES: Commander, U.S. Army Medical Research and Materiel Command, ATTN: Command Judge Advocate, MCMR–JA, 504 Scott Street, Fort Detrick, Frederick, Maryland 21702–5012.

FOR FURTHER INFORMATION CONTACT: For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619–7808. For licensing issues, Dr. Paul Mele, Office of Research & Technology Assessment, (301) 619–6664. Both at telefax (301) 619–5034.

SUPPLEMENTARY INFORMATION: A material comprising a porous support and a plurality of enzymes for the removal, decontamination or neutralization of hazardous chemicals such as OP compounds is disclosed. The material may be used on a variety of surfaces, including natural, synthetic, and biological surfaces such as skin and other delicate membranes. Also disclosed is a process of making the material, kits and various methods and reactivation devices for reactivating the enzymatic activity of the material.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–18009 Filed 7–18–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Availability for Non-Exclusive, Exclusive, or Partially Exclusive Licensing of U.S. Patent Concerning Compositions for Use To Deactivate Organophosphates

AGENCY: U.S. Army Medical Research and Materiel Command, DoD.

ACTION: Notice.

SUMMARY: In accordance with 37 CFR 404.6, announcement is made of the availability for licensing of U.S. Patent 5,695,750 entitled ''Compositions for Use to Deactivate Organophosphates'' issued December 9, 1997. This patent has been assigned to the United States Government as represented by the Secretary of the Army.

ADDRESSES: Commander, U.S. Army Medical Research and Materiel Command, ATTN: Command Judge Advocate, MCMR–JA, 504 Scott Street, Fort Detrick, Frederick, Maryland 21702–5012.

FOR FURTHER INFORMATION CONTACT: For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619–7808. For licensing issues, Dr. Paul Mele, Office of Research & Technology Assessment, (301) 619–6664. Both at telefax (301) 619–5034.

SUPPLEMENTARY INFORMATION: A method of detoxifying organophosphates using mutant cholinesterase which resists aging. The addition of oximes to the cholinesterase further retards aging of the cholinesterase.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–18007 Filed 7–18–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Defense Logistics Agency

Privacy Act of 1974; Computer Matching Program

AGENCY: Defense Manpower Data Center, Defense Logistics Agency, DOD.

ACTION: Notice of a computer matching program.

SUMMARY: Subsection (e)(12) of the Privacy Act of 1974, as amended, (5 U.S.C. 552a) requires agencies to publish advance notice of any proposed or revised computer matching program by the matching agency for public comment. The Department of Defense (DoD), as the matching agency under the Privacy Act, is hereby giving constructive notice in lieu of direct notice to the record subjects of a computer matching program between the Department of the Treasury and DoD that their records are being matched by computer. The record subjects are delinquent debtors of the Bureau of the Public Debt., Department of the Treasury, who are current or former Federal employees receiving any Federal salary or benefit payments and who are indebted or delinquent in their repayment of debts to the United States Government under certain programs administered by the Public Debt.

DATES: This proposed action will become effective August 20, 2001 and matching may commence unless changes to the matching program are required due to public comments or by Congressional or by Office of Management and Budget objections. Any public comment must be received before the effective date.

ADDRESSES: Any interested party may submit written comments to the Director, Defense Privacy Office, 1941 Jefferson Davis Highway, Suite 920, Arlington, VA 22202–4502.

FOR FURTHER INFORMATION CONTACT: Mr. Vahan Moushegian, Jr. at (703) 607–2943.

SUPPLEMENTARY INFORMATION: Pursuant to subsection (o) of the Privacy Act of 1974, as amended, (5 U.S.C. 552a), the Department of the Treasury and the Defense Manpower Data Center (DMDC) have concluded an agreement to conduct a computer matching program. The purpose of the match is to exchange personal data between the agencies for debt collection. The match will yield the identity and location of the debtors within the Federal Government so that the Bureau can pursue recoupment of the debt by voluntary payment or by administrative or salary offset procedures. Computer matching appeared to be the most efficient and effective manner to accomplish this task with the least amount of intrusion of personal privacy of the individuals concerned. It was therefore concluded and agreed upon that computer matching would be the best and least obtrusive manner and choice for accomplishing this requirement.

A copy of the computer matching agreement between the Department of the Treasury and DMDC is available to the public upon request. Requests should be submitted to the address caption above or to the Debt Collection Officer, Bureau of Public Debt, Hintgen Building, Room 114, P.O. Box 1328, Parkersburg, WV 26106–1328.

Set forth below is the notice of the establishment of the computer matching program required by paragraph 6.c. of the Office of Management and Budget Guidelines on computer matching published on June 19, 1989, at 54 FR 25818.

The matching agreement, as required by 5 U.S.C. 552a(r) of the Privacy Act, and an advance copy of this notice was submitted on July 10, 2001, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget pursuant to paragraph 4d 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: July 13, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

COMPUTER MATCHING PROGRAM BETWEEN THE DEPARTMENT OF THE TREASURY/BUREAU OF PUBLIC DEBT, AND THE DEFENSE MANPOWER DATA CENTER, DEPARTMENT OF DEFENSE FOR DEBT COLLECTION

A. PARTICIPATING AGENCIES:

Participants in this computer matching program are the Bureau of Public Debt, Department of the Treasury and the Defense Manpower Data Center (DMDC), Department of Defense (DoD). The Bureau of Public Debt is the source agency, i.e., the agency disclosing the records for the purpose of the match. DMDC is the specific recipient or matching agency, i.e., the agency that actually performs the computer matching.

B. PURPOSE OF THE MATCH:

The purpose of the match is to identify and locate any matched Federal personnel, employed, serving or retired, who owe delinquent debts to the Federal Government under certain programs administered by the Bureau of Public Debt. The Bureau will use this information to initiate independent collection of those debts under the provisions of the Debt Collection Act of 1982, as amended, when voluntary payment is not forthcoming. These collection efforts will include requests by the Bureau of the military service/employing agency in the case of military personnel (either active, reserve, or retired) and current non-postal civilian employees, and to the Office of Personnel Management in the case of retired non-postal civilian employees to apply administrative and/or salary offset procedures until such time as the obligation is paid in full.

C. AUTHORITY FOR CONDUCTING THE MATCH:

The legal authority for conducting the matching program is contained in the Debt Collection Act of 1982 (Pub. L. 97–365), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134, section 31001); 31 U.S.C. chapter 37, subchapter I (General) and subchapter II (Claims of the United States Government); 31 U.S.C. 3711, Collection and Compromise; 31 U.S.C. 3716, Administrative Offset; 5 U.S.C. 5514, Installment Deduction for Indebtedness (Salary Offset); 10 U.S.C. 135, Under Secretary of Defense (Comptroller); Section 101(1) of Executive order 12731; 31 CFR chapter IX, Federal Claims Collection Standards; 5 CFR 550.1101–550.1108 Collection by Offset from Indebted Government Employees (OPM); 31 CFR part 5, subparts B & D (Department of Treasury).

D. RECORDS TO BE MATCHED:

The systems of records maintained by the respective agencies under the Privacy Act of 1974, as amended, from which records will be disclosed for the purpose of this computer match are as follows:

1. The Bureau of Public Debt will use personal data from the following record systems for the match:

a. Record system identified as Treasury/BPD.001, entitled 'Human Resources and Administrative Records,' last published in the **Federal Register** at 66 FR 28222, May 22, 2001.

b. Record system identified as Treasury/BPD.002, entitled 'United States Savings-Type Securities,' last published in the **Federal Register** at 66 FR 28224, May 22, 2001.

c. Record system identified as Treasury/BPD.003 entitled 'United States Securities (other than Savings-type Securities),' last published in the **Federal Register** at 66 FR 28227, May 22, 2001.

d. Record system identified as Treasury/DO.002, entitled ''Treasury Integrated Management Information Systems (TIMIS),' last published in the **Federal Register** at 63 FR 69719, December 17, 1998.

e. Record system identified as Treasury/DO.210, entitled 'Treasury Integrated Financial Management and Revenue System,' last published in the **Federal Register** at 63 FR 69741, December 17, 1998.

f. Record system identified as Treasury/DO.211 entitled 'Telephone Call Detail Records,' last published in the **Federal Register** at 63 FR 69743, December 17, 1998.

2. DOD will use personal data from the record system identified as S322.11 DMDC, entitled 'Federal Creditor Agency Debt Collection Database,' last published in the **Federal Register** at 64 FR 42101, August 3, 1999.

E. DESCRIPTION OF COMPUTER MATCHING PROGRAM:

The Bureau of Public Debt, as the source agency, will provide DMDC with an electronic file which contains the names of delinquent debtors in programs the Bureau administers. Upon receipt of the electronic file of debtor accounts, DMDC will perform a computer match using all nine digits of the SSN of the Bureau's file against a DMDC computer database. The DMDC database, established under an interagency agreement between DOD, OPM, OMB and the Treasury Department, consists of employment records of non-postal Federal employees and military members, active and retired. The 'hits' or matches will be furnished to the Bureau. The Bureau is responsible for verifying and determining that the data on the DMDC reply tape file are consistent with the Bureau's source file and for resolving any discrepancies or inconsistencies on an individual basis. The Bureau will also be responsible for making final determinations as to positive identification, amount of indebtedness and recovery efforts as a result of the match.

The electronic file provided by the Bureau of Public Debt will contain data elements of the debtor's name, SSN, internal account numbers and the total amount owed for each debtor on approximately 3400 delinquent debtors. The electronic file provided by DMDC will contain an individual's name, SSN, military service or employing agency and current work or home address.

The DMDC computer database file contains approximately 4.8 million records of active duty and retired military members, including Reserve and Guard, and approximately 3.1 million records of active and retired non-postal Federal civilian employees.

F. INCLUSIVE DATES OF THE MATCHING PROGRAM:

This computer matching program is subject to review by the Office of Management and Budget and Congress. If the mandatory 30 day period for public comment has expired and if no objections are raised by either Congress or the Office of Management and Budget within 40 days of being notified of the proposed match, the computer matching program becomes effective and the respective agencies may begin the exchange of data at a mutually agreeable time on an annual basis. By agreement between the Department of the Treasury and DoD, the matching program will be in effect and continue for 18 months with an option to extend for 12 additional months unless one of the parties to the agreement advises the other by written request to terminate or modify the agreement.

H. ADDRESS FOR RECEIPT OF PUBLIC COMMENTS OR INQUIRIES:

Director, Defense Privacy Office, 1941 Jefferson Davis Highway, suite 920, Arlington, VA 22202–4502. Telephone (703) 607–2943.

[FR Doc. 01–18061 Filed 7–18–01; 8:45 am]

BILLING CODE 5001–08–M

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Intent To Prepare an Environmental Impact Statement (EIS) on an Application for a Department of the Army Permit Under Section 404 of the Clean Water Act by Alcoa Inc. for Construction and Operation of the Three Oaks Surface Lignite Mine in Lee and Bastrop Counties, TX

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The U.S. Army Corps of Engineers, Fort Worth District (USACE), intends to prepare an Environmental Impact Statement (EIS) to assess the environmental, social, and economic effects of issuance of a Department of the Army permit under Section 404 of the Clean Water Act for discharges of dredged and fill material into waters of the United States associated with the proposed construction and operation of a surface lignite mine. In the EIS, the USACE will assess potential impacts associated with a range of alternatives.

FOR FURTHER INFORMATION CONTACT: For further information and/or questions about the proposed action and EIS, please contact Ms. Jennifer Walker, Regulatory Project Manager, by letter at Regulatory Branch, CESWF–PER–R, U.S. Army Corps of Engineers, P.O. Box 17300, Fort Worth, Texas 76102–Texas 76102–0300 or by telephone at (817) 978–7547.

SUPPLEMENTARY INFORMATION:

1. Description of the Proposed Project: The applicant, Alcoa, Inc. (Alcoa), proposes to construct and operate the Three Oaks Lignite Mine in Lee and Bastrop Counties, Texas. The Three Oaks Mine lands are in the Brazos and Colorado River basins in east central Texas. The mine would be located to recover lignite from the Wilcox lignite belt, and would be located adjacent to the Alcoa Sandow Mine, which lies immediately to the Northeast of the proposed mine near Rockdale, in Milam and Lee Counties, Texas. The Sandow Mine has been operated by Alcoa since the early 1950s.

Alcoa currently intends to supply approximately 6 million tons per year of lignite to electric power generation plants owned by Alcoa and TXU that supply power to the Alcoa Rockdale Aluminum Smelter. A portion of the electricity generated by TXU is distributed over the TXU electric grid. At a rate of 6 million tons per year, Alcoa estimates that the proposed mine contains over 30 years of lignite fuel for these purposes.

Based upon current mining technologies and costs and the current rate of mining, the Sandow Mine will reach the end of its useful life in approximately five years. The primary purpose of Alcoa's proposed Three Oaks Mine is to continue to provide to provide a long-term source of energy to allow the continued operation of Alcoa's Rockdale aluminum smelter. Alcoa has stated that, to serve this purpose, the energy source must meet the following criteria: (1) Generate, or be used to generate, sufficient amounts of electricity, (2) be delivered to the smelter at a total cost that is stable, predictable, and low enough to sustain the economic viability of the smelter, (3) be available on a secure, firm, and continuous basis over a 30 year period, and (4) be available for use when the existing Sandow Mine is no longer a source of economically-recoverable lignite reserves (five years).

The USACE has received an application for a Department of the Army permit under Section 404 of the Clean Water Act from Alcoa to construct and operate the proposed mine. In accordance with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*) the USACE has determined that issuance of such a permit may have a significant impact on the quality of the human environment and, therefore, requires the preparation of an EIS.

2. Alternatives: Alternatives available to the USACE are to: (1) Issue the Department of the Army permit; (2) issue the Department of the Army permit with special conditions; or (3) deny the Department of the Army permit. Alternatives available to Alcoa include: (1) Constructing and operating the new Three Oaks Mine as proposed by Alcoa; (2) constucting and operating the new Three Oaks Mine as proposed by Alcoa, with modifications; (3) developing or acquiring other energy sources, including purchasing power from the electrical grid, converting the existing power plants to utilize western coal, or converting to the use of natural gas; or (4) no action.

3. Scoping and Public Involvement Process: A public meeting (open house format) to gather information on the scope of the EIS, including the issues to be addressed in detail in the document will be conducted on August 21, 2001, form 3 to 9 p.m at the American Legion Hall located oin the south side of U.S. Highway 77, one mile south of U.S. Highway 290, in Giddings, Texas.

4. Significant Issues: Issues to be given significant analysis in the EIS are likely to include, but will not be limited to: The effects of mining activities on the mine's neighbors and nearby communities; streams, wetlands, surface water quantity and quality, groundwater quantity and quality, geologic resources, vegetation, fish and wildlife, threatened and endangered species, soils, prime farmland, noise, light, aesthetics, historic and pre-historic cultural resources, socioeconomics, land use, public roads, and air quality.

5. Cooperating Agencies: At this time, no other federal or state agencies are expected to be cooperating agencies in preparation of the EIS. However, numerous federal and state agencies, including the U.S. Office of Surface Mining, the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the Railroad Commission of Texas, the Texas Natural Resource Conservation Commission, the Texas Parks and Wildlife Department are expected to be involved in the preparation of, and provide comments on, the EIS.

6. Additional Review and Consultation: Compliance with other federal and state requirements that will be addressed in the EIS include, but will not be limited to, state water quality certification under Section 401 of the Clean Water Act, compliance with the Railroad Commission of Texas regulations regarding surface coal mining, protection of water quality under the Texas Pollutant Discharge Elimination System, protection of air quality under the Texas Air Quality Act, protection of endangered and threatened species under Section 7 of the Endangered Species Act, and protection of cultural resources under Section 106 of the National Historic Preservation Act.

7. Availability of the Draft EIS: The Draft EIS is projected to be available by April 2002. A public hearing will be conducted following the release of the Draft EIS.

Dated: July 12, 2001.

Gordon M. Wells,

Colonel, Corps of Engineers, District Engineer.

[FR Doc. 01–18013 Filed 7–18–01; 8:45 am]

BILLING CODE 3710–20–M

DEPARTMENT OF EDUCATION

Arbitration Panel Decision Under the Randolph-Sheppard Act

AGENCY: Department of Education.

ACTION: Notice of arbitration panel decision under the Randolph-Sheppard Act.

SUMMARY: Notice is hereby given that on December 26, 2000, an arbitration panel rendered a decision in the matter of *California Department of Rehabilitation* v. *General Services Administration (Docket No. R–S/99–1).* This panel was convened by the U.S. Department of Education pursuant to 20 U.S.C. 107d–1(b) upon receipt of a complaint filed by petitioner, the California Department of Rehabilitation.

FOR FURTHER INFORMATION: A copy of the full text of the arbitration panel decision may be obtained from George F. Arsnow, U.S. Department of Education, 400 Maryland Avenue, SW., room 3230, Mary E. Switzer Building, Washington, DC 20202–2738. Telephone: (202) 205–9317. If you use a telecommunications device for the deaf (TDD), you may call the TDD number at (202) 205–8298.

Individuals with disabilities may obtain this document in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

Electronic Access to This Document:

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *www.ed.gov/legislation/FedRegister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html.*

SUPPLEMENTARY INFORMATION: Pursuant to section 6(c) of the Randolph-Sheppard Act (the Act), 20 U.S.C. 107d–2(c), the Secretary publishes in the **Federal Register** a synopsis of each arbitration panel decision affecting the administration of vending facilities on Federal and other property.

Background

This dispute concerns the alleged improper termination by the General Services Administration (GSA) of a vending permit held by the California Department of Rehabilitation, the State licensing agency (SLA), at the Roybal Building in Los Angeles, California, pursuant to the provisions of the Act (20 U.S.C. 107 *et seq.*) and the implementing regulations in 34 CFR part 395.

A summary of the facts is as follows: On August 3, 1993, the SLA and GSA entered into a permit agreement to establish a vending facility, including vending machines, at the Roybal Building, 255 East Temple Street, Los Angeles, California. The SLA assigned a permanent vendor to this location with the participation and approval of GSA.

Initially the services provided at the Roybal building consisted primarily of vending machines, but in 1996 GSA remodeled its lobby area to construct a larger facility that provided customers with coffee and various other food items. After completing the remodeling of the vending facility, GSA cancelled the 1993 permit and issued a new permit to the SLA to operate the remodeled facility in the lobby. It was the position of GSA that the newer remodeled facility constituted a new facility that warranted the SLA to conduct a selection process for a vendor to manage the remodeled facility.

Conversely, the SLA took the position that GSA had no right to cancel the 1993 vending permit and that the remodeled facility was not a new facility within the meaning of State rules and regulations that would provide for a new vendor selection process.

The SLA alleged that the real issue focused on GSA's complaint that the vendor, who had been providing service prior to the remodeling of the vending facility, was considered by GSA to be unqualified and unacceptable to manage the remodeled vending facility. The SLA further alleged that GSA demanded that the SLA initiate a selection process for a new vendor to manage the remodeled vending facility only after the facility had been remodeled.

Following the cancellation of the 1993 permit and the SLA's refusal to place another vendor at the facility, GSA awarded a contract to a private concessionaire to operate the Roybal vending facility.

Arbitration Panel Decision

The panel, after considering all of the evidence, ruled that GSA violated the Act and implementing regulations. GSA had no authority to unilaterally cancel the vending permit agreement signed in 1993 between itself and the SLA, since there was no evidence of noncompliance by the SLA with its terms. GSA's issuance of a new permit in 1996 was simply an updated version of the original permit agreement between GSA and the SLA in 1993.

The panel further stated that the new 1996 permit, which essentially upgraded the 1993 permit, obligated GSA to provide a vending facility at the Roybal Building to the SLA so that it could place a qualified blind vendor pursuant to the Act. Additionally, the SLA's original blind vendor had the right to continue to operate the relocated vending facility.

The violations of the Act and the regulations by GSA caused both the SLA and the blind vendor to suffer damages. The damages to the SLA include loss of revenue generated from the blind vendor, which amounts to 6 percent of the net proceeds of the blind vendor. The SLA is also entitled to a fair market rental for its equipment during the time it was being used by GSA.

Finally, the panel instructed GSA that it had 30 days from the date of the panel's decision to provide the SLA with evidence of the blind vendor's lack of qualifications to operate the Roybal Building vending facility; otherwise, GSA would be liable for damages to the blind vendor. The panel ruled that the damages would be the difference between what he had been able to earn and what the private concessionaire earned during the transition period when the SLA was not managing the Roybal Building vending facility, plus interest.

The views and opinions expressed by the panel do not necessarily represent the views and opinions of the U.S. Department of Education.

Dated: July 16, 2001.

Francis V. Corrigan,

Deputy Director, National Institute on Disability and Rehabilitation Research.

[FR Doc. 01–18072 Filed 7–18–01; 8:45 am]

BILLING CODE 4000–01–U

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meeting be announced in the **Federal Register.**

DATES: Friday, August 3, 2001—3:30 p.m.–9 p.m.

Saturday, August 4, 2001—8 a.m.–4 p.m.

ADDRESSES: Rothchild's, 8807 Kingston Pike, Knoxville, TN.

FOR FURTHER INFORMATION CONTACT: Pat Halsey, Federal Coordinator, Department of Energy Oak Ridge Operations Office, P.O. Box 2001, EM–922, Oak Ridge, TN 37831. Phone (865) 576–4025; Fax (865) 576–5333 or e-mail: *halseypj@oro.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board

The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

1. Annual Retreat To Plan the FY 2002 Workplan

Public Participation

The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Pat Halsey at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of five minutes to present their comments at the end of the meeting.

Minutes

Minutes of this meeting will be available for public review and copying at the Department of Energy's Information Resource Center at 105 Broadway, Oak Ridge, TN between 7:30 a.m. and 5:30 p.m. Monday through Friday, or by writing to Pat Halsey, Department of Energy Oak Ridge Operations Office, P.O. Box 2001, EM–922, Oak Ridge, TN 37831, or by calling her at (865) 576–4025.

Issued at Washington, DC on July 16, 2001.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 01–18057 Filed 7–18–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Rocky Flats

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Rocky Flats. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meeting be announced in the **Federal Register.**

DATE: Thursday, August 2, 2001—6 p.m. to 9:30 p.m.

ADDRESSES: Broomfield City Hall, One DesCombes Drive, Broomfield, CO.

FOR FURTHER INFORMATION CONTACT: Ken Korkia, Board/Staff Coordinator, Rocky Flats Citizens Advisory Board, 9035 North Wadsworth Parkway, Suite 2250, Westminster, CO, 80021; telephone (303) 420–7855; fax (303) 420–7579.

SUPPLEMENTARY INFORMATION:

Purpose of the Board

The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

1. Quarterly update by the Colorado Department of Public Health and Environment
2. Final recommendation on Environmental Restoration Rocky Flats Cleanup Agreement (RFCA) Standard Operating Protocol (RSOP) document for the Board's review and approval
3. Second part of Board recommendation development and ongoing educational discussion regarding the Radionuclide Soil Action Level Review
4. Other Board business may be conducted as necessary

Public Participation

The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Ken Korkia at the address or telephone number listed above. Requests must be received at least five days prior to the meeting and reasonable provisions will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes

The minutes of this meeting will be available for public review and copying at the Public Reading Room located at the Office of the Rocky Flats Citizens Advisory Board, 9035 North Wadsworth Parkway, Suite 2250, Westminister, CO 80021; telephone (303) 420–7855. Hours of operations for the Public Reading Room are 9 a.m. to 4 p.m., Monday–Friday, except Federal holidays. Minutes will also be made available by writing or calling Deb Thompson at the address or telephone number listed above.

Issued at Washington, DC on July 16, 2001.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 01–18058 Filed 7–18–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–2074–000]

Calhoun Power Company I, LLC; Notice of Issuance of Order

July 13, 2001.

Calhoun Power Company I, LLC (Calhoun) filed with the Commission, in the above-docketed proceeding, a proposed tariff under which Calhoun will engage in the sale of wholesale electric capacity, energy, and certain ancillary services at market-based rates, and a long-term service agreement with Alabama Power Company. Calhoun's filing also requested certain waivers and authorizations. In particular, Calhoun requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liabilities by Calhoun. On July 12, 2001, the Commission issued an order that accepted the tariff for sales of capacity and energy at market-based rates (Order), in the above-docketed proceeding.

The Commission's July 12, 2001 Order granted Calhoun's request for blanket approval under part 34, subject to the conditions found in Appendix A in Ordering Paragraphs (2), (3), and (5):

(2) Within 30 days of the date of this order, any person desiring to be heard or to protest the Commission's blanket approval of issuances of securities or assumptions of liabilities by Calhoun should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211 and 385.214.

(3) Absent a request to be heard within the period set forth in Paragraph

(2) above, Calhoun is hereby authorized to issue securities and assume obligations and liabilities as guarantor, indorser, surety or otherwise in respect of any security of another person; provided that such issue or assumption is for some lawful object within the corporate purposes of Calhoun, compatible with the public interest, and reasonably necessary or appropriate for such purposes.

(5) The Commission reserves the right to modify this order to require a further showing that neither public nor private interests will be adversely affected by continued Commission approval of Calhoun's issuances of securities or assumptions of liabilities. * * *

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is August 13, 2001.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC. 20426. The Order may also be viewed on the on the web at http://www.ferc.gov using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

David P. Boergers

Secretary.

[FR Doc. 01–18023 Filed 7–18–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–483–000]

Natural Gas Pipeline Company of America; Notice of Proposed Changes in FERC Gas Tariff

July 13, 2001.

Take notice that on July 10, 2001, Natural Gas Pipeline Company of America (Natural) tendered for filing to become part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the tariff sheets listed on Appendix A to the filing, to be effective August 10, 2001.

Natural states that these sheets were filed to revise several rate schedules and the General Terms and Conditions of Natural's Tariff by making minor updates in four areas by: (1) Making a minor change to Natural's provision for scheduling interruptible services, (2) eliminating from Natural's service request procedures in various rate schedules certain data elements which are no longer relevant, (3) revising the information which may be kept confidential in a capacity release to reflect the Federal Energy Regulatory Commission's transactional posting requirements and (4) correcting several tariff sheets by eliminating duplicative language and an outdated section reference.

Natural states that copies of the filing are being mailed to its customers and interested state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

David P. Boergers,

Secretary.

[FR Doc. 01–18032 Filed 7–18–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–2536–000]

New York Independent System Operator, Inc.; Notice of Filing

July 13, 2001.

Take notice that the New York Independent System Operator, Inc. (NYISO) on July 6, 2001 tendered for filing proposed revisions to Sections 5.9–5.16 of its Market Administration and Control Area Services Tariff. The NYISO requests an effective date of 60 days after this filing (September 4, 2001). Take further notice that the NYISO has requested on behalf of the Market Participants that the Commission determine the appropriate translation from Installed Capacity to Unforced Capacity of the $105 cap applicable to In-City generators subject to market power mitigation measures previously adopted by the Commission.

Copies of this filing were served upon all persons who have executed Service Agreements under the ISO Market Services Tariff and all parties included on the service list for Docket No. ER98–3169–000.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests regarding translation of the $105 cap should be filed on or before July 20, 2001. All such motions and protests regarding proposed revisions to Sections 5.9–5.16 should be filed on or before July 27, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-filing'' link.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–18027 Filed 7–18–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–153–001]

Tuscarora Gas Transmission Company; Notice of Amendment

July 13, 2001.

Take notice that on July 6, 2001, Tuscarora Gas Transmission Company (Tuscarora), 1575 Delucchi Lane, Suite

225, Reno, Nevada 89520–3057, filed in Docket No. CP01–153–001, an amendment to its initial application for a certificate of public convenience and necessity filed in Docket No. CP01–153–000. With this amendment, Tuscarora is requesting authority to install, own, operate and maintain a booster unit rated at 637 horsepower and appurtenant facilities as part of Tuscarora's 2002 Expansion Project, all as more fully set forth in the application which is on file with the Commission and open to public inspection. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance).

Tuscarora states that it is also filing modified Transportation Service Agreements between Tuscarora and Southwest Gas Corporation as described more fully in the amendment.

Tuscarora states that it filed the initial application for the 2002 Expansion Project on April 12, 2001 for authorization to construct, install, own, operate and maintain facilities necessary to render up to 95,912 dekatherms per day (Dth/d) of firm transportation service to four Expansion Shippers: Sierra Pacific Power Company, Southwest Gas Corporation, Duke Energy North America, L.L.C., and Morgan Stanley Capital Group Inc.

Tuscarora states that this amendment will not affect the total capacity under contract for the 2002 Expansion Project, nor the showing of market need reflected in the initial application. According to Tuscarora, the booster unit proposed in this amendment will be located within the new Paiute Interconnect Meter Station proposed as part of the 2002 Expansion Project and will not require additional land acquisition or ground disturbance. Tuscarora states that since the cost of the booster unit is estimated to be approximately $770,000, the proposed facilities will not affect the overall cost/revenue analysis. According to Tuscarora, this amendment will not affect the total capacity created by the 2002 Expansion Project or the construction schedule proposed in the April 12, 2001 application. Tuscarora states that it proposes to install the booster unit simultaneously with other facilities proposed in the 2002 Expansion Project, commencing in or about April 2002 to meet the first of its Expansion Shippers' in-service dates of November 1, 2002.

Any questions regarding this amendment should be directed to Terry Wolverton, Tuscarora Gas Transmission Company, 1575 Delucchi Lane, Suite 225, P.O. Box 30057, Reno, Nevada 89520–3057, call (775) 834–4292, or fax (775) 834–3886.

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 August 3, 2001, 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.

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.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

David P. Boergers,

Secretary.

[FR Doc. 01–18026 Filed 7–18–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF00–2012–001, et al.]

U.S. Department of Energy, *et al.*; Electric Rate and Corporate Regulation Filings

July 13, 2001.

Take notice that the following filings have been made with the Commission:

1. U.S. Department of Energy Bonneville Power Administration

[Docket No. EF00–2012–001]

Take notice that on June 29, 2001, the Bonneville Power Administration (BPA) tendered for filing with the Federal

Energy Regulatory Commission (Commission) proposed supplemental wholesale power rate adjustments pursuant to section 7(a)(2) of the Pacific Northwest Electric Power Planning and Conservation Act, 16 U.S.C. 839e(a)(2).

BPA seeks interim approval of its proposed rates effective October 1, 2001, pursuant to the Commission's regulation 300.20, 18 CFR 300.20. Pursuant to Commission's regulation 300.21, 18 CFR 300.21, BPA seeks interim approval and final confirmation of the proposed rates for the periods set forth in this notice.

BPA requests approval effective October 1, 2001, through September 30, 2006, for the following proposed wholesale power rates: PF–02 Priority Firm Power Rate, RL–02 Residential Load Firm Power Rate, NR–02 New Resource Firm Power Rate, IP–02 Industrial Firm Power Rate, including the IPTAC, and NF–02 Nonfirm Energy Rate. In addition, BPA requests approval of the adjusted General Rate Schedule Provisions (GRSPs) for the period October 1, 2001, through September 30, 2006. The GRSPs apply to the 2002 wholesale power rates. BPA requests approval of the methodology used to calculate the rate for the Slice product sold under the PF rate schedule for the period October 1, 2001, through September 30, 2011.

Comment date: August 3, 2001, in accordance with Standard Paragraph E at the end of this notice.

2. Jackson County Power, LLC

[Docket No. EG01–261–000]

Take notice that on July 11, 2001, Jackson County Power, LLC tendered for filing with the Federal Energy Regulatory Commission (Commission) an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

The applicant is a limited liability company organized under the laws of the State of Delaware that is engaged directly and exclusively in developing, owning, and operating a gas-fired 1,072 MW combined cycle power plant in Jackson County, Ohio, six miles south of Jackson, Ohio, which will be an eligible facility.

Comment date: August 5, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

3. PPL Large Scale Distributed Generation II, LLC

[Docket No. EG01–262–000]

Take notice that on July 12, 2001, PPL Large Scale Distributed Generation II, LLC (the Applicant), filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

The Applicant is a Delaware limited liability company that will lease one or more ''eligible facilities'', as defined under PUHCA, including facilities to be located in Arizona, Pennsylvania and Illinois, which it will lease from Large Scale Distributed Generation II Statutory Trust.

Comment date: August 3, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

4. Large Scale Distributed Generation II Statutory Trust

[Docket No. EG01–263–000]

Take notice that on July 12, 2001, Large Scale Distributed Generation II Statutory Trust (the Applicant) filed with the Federal Energy Regulatory Commission (Commission) an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

The Applicant is a Connecticut statutory trust that will own one or more ''eligible facilities'', as defined under PUHCA, including facilities to be located in Arizona, Pennsylvania and Illinois, which it will lease to PPL Large Scale Distributed Generation II, LLC.

Comment date: August 3, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

5. Cleco Power LLC

[Docket No. ER01–1099–005]

Take notice that Cleco Power LLC (Cleco Power), on July 10, 2001, tendered for filing a substitute original Rate Schedule 12. On June 23, 2001, Cleco Utility's Rate Schedule 15 was canceled and refiled as Cleco Power Rate Schedule 12. Appendix C was inadvertently omitted from Cleco Power's Rate Schedule 12; accordingly, Cleco Power filed a substitute original Rate Schedule 12 that includes Appendix C.

Comment date: July 31, 2001, in accordance with Standard Paragraph E at the end of this notice.

6. Michigan Electric Transmission Company

[Docket No. ER01–2126–001]

Take notice that on July 9, 2001, Michigan Electric Transmission Company tendered for filing an amendment to its original filing in this docket in response to a deficiency letter dated July 2, 2001.

Copies of the filing were served upon FERC Staff and those on the official service list in this proceeding.

Comment date: July 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

7. Exelon Generation Company, LLC

[Docket No. ER01–2549–000]

Take notice that on July 10, 2001, Exelon Generation Company, LLC (Exelon Generation) submitted for filing with the Federal Energy Regulatory Commission (FERC or the Commission) a service agreement for wholesale power sales transactions between Exelon Generation and WPS Energy Services, Inc. under Exelon Generation's wholesale power sales tariff, FERC Electric Tariff, Original Volume No. 1.

Exelon Generation requests that the Service Agreement be accepted for filing effective as of April 1, 2001.

Comment date: July 31, 2001, in accordance with Standard Paragraph E at the end of this notice.

8. Deseret Generation and Transmission Co-operative, Inc.

[Docket No. ER01–2550–000]

Take notice that on July 10, 2001, Deseret Generation & Transmission Co-operative, Inc. (Deseret) tendered for filing an executed Confirmation Agreement for a firm power sale between Deseret and Utah Associated Municipal Power Systems (UAMPS). This Confirmation Agreement is filed pursuant to the Western Systems Power Pool Agreement regarding a long-term power purchase and sale transaction. Deseret requests an effective date of July 1, 2001.

Comment date: July 31, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. Cincinnati Gas & Electric Company

[Docket No. ER01–2551–000]

Take notice that on July 10, 2001, Cincinnati Gas & Electric Company (CG&E) submitted an application for reclassification of its transmission and distribution facilities as required by the Ohio Public Utilities Commission. In accordance with the seven-factor test established by the Commission in Order No. 888, CG&E proposes to designate all of its directly-owned Ohio facilities

operated at 69 kV and above as FERC-jurisdictional transmission facilities and to designate all of its remaining Ohio facilities as state-jurisdictional distribution facilities. The sole purpose of this application is to facilitate unbundled retail transmission in the state of Ohio. CG&E does not seek in this application to adjust its service rates.

Comment date: July 31, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. Central Maine Power Company

[Docket No. ER01–2552–000]

Take notice that Central Maine Power Company (CMP), on July 10, 2001, tendered for filing pursuant to Section 205 of the Federal Power Act (FPA) of the Federal Energy Regulatory Commission (Commission or FERC), an Amendment to System Contract Entitlement Agreement (Amendment) between CMP and Engage Energy America LLC (Engage) and, in compliance with Order No. 614, FERC Stats. & Regs. 31,096 (2000), a First Revised System Contract Entitlement Agreement between CMP and Engage (First Revised Agreement), revised pursuant to the Amendment.

CMP respectfully requests that the Commission accept the Amendment and the First Revised Agreement effective as of June 26, 2001, without modification or condition, and grant waiver of any and all requirements, including the Commission's notice requirements for good cause, for both agreements to become effective. Copies of this filing have been served on Engage and the State of Maine Public Utilities Commission.

Comment date: July 31, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. Lakefield Junction, L.P.

[Docket No. ER01–2553–000]

Take notice that on July 10, 2001, Lakefield Junction, L.P. tendered for filing under its market-based rate tariff a long-term service agreement with Great River Energy.

Comment date: July 31, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Northeast Utilities Service Company

[Docket No. ER01–2556–000]

Take notice that Northeast Utilities Service Company (NUSCO), on July 9, 2001, tendered for filing, Service Agreement to provide Firm Point-To-Point Transmission Service to Select Energy Inc. under the NU System Companies' Open Access Transmission Service Tariff No. 9. NUSCO states that a copy of this filing has been mailed to Select Energy Inc.

NUSCO requests that the Service Agreement become effective September 1, 2001.

Comment date: July 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

13. Northeast Utilities Service Company

[Docket No. ER01–2557–000]

Take notice that on July 9, 2001, Northeast Utilities Service Company (NUSCO), on tendered for filing, Service Agreement to provide Non-Firm Point-To-Point Transmission Service to Select Energy Inc. under the NU System Companies' Open Access Transmission Service Tariff No. 9. NUSCO states that a copy of this filing has been mailed to Select Energy Inc.

NUSCO requests that the Service Agreement become effective September 1, 2001.

Comment date: July 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

14. Golden Spread Electric Cooperative, Inc.

[Docket No. ER01–2558–000]

Take notice that on July 10, 2001, Golden Spread Electric Cooperative, Inc. (Golden Spread) tendered for filing with the Commission an Informational Filing to Rate Schedule No. 35. The Informational Filing updates the formulary fixed costs associated with replacement energy sales by Golden Spread to the customer, Southwestern Public Service Company (Southwestern). Golden Spread has also submitted the filing in an Order No. 614 compliant format. A copy of this filing has been served upon Southwestern.

Comment date: July 31, 2001, in accordance with Standard Paragraph E at the end of this notice.

15. ISO New England Inc.

[Docket No. ER01–2559–000]

Take notice that on July 10, 2001, ISO New England Inc., submitted as a Section 205 filing in the above Docket a new proposal for eliminating the external contract floor price, effective September 1, 2001.

Comment date: July 31, 2001, in accordance with Standard Paragraph E at the end of this notice.

16. Western Resources, Inc.

[Docket No. ER01–2570–000]

Take notice that on July 10, 2001, Western Resources, Inc. (Western Resources) tendered for filing a Service Agreement between Western Resources and the cities of Burlingame, Clay Center, Ellinwood, Herington, Holton, Larned, Minneapolis, Osage City, Sabetha, Stafford, Sterling and Wamego, Kansas (Cities). Western Resources states that the purpose of these agreements is to permit the Cities to take service under Western Resources' Market Based Power Sales Tariff on file with the Commission. This agreement is proposed to be effective June 15, 2001.

Copies of the filing were served upon the Kansas Corporation Commission and the Cities.

Comment date: July 31, 2001, in accordance with Standard Paragraph E at the end of this notice.

17. Duke Energy Corporation/Duke Energy Fossil-Hydro, LLC/Duke Energy Nuclear, LLC

[Docket No. EL01–101–000]

Take notice that on July 10, 2001, Duke Energy Corporation d/b/a Duke Power (Duke Power), Duke Energy Fossil-Hydro, LLC (Duke Fossil) and Duke Energy Nuclear, LLC (Duke Nuclear) filed a petition with the Commission for a declaratory order (i) disclaiming jurisdiction under Sections 201(e) and 205 of the Federal Power Act (FPA) over Duke Fossil and Duke Nuclear with respect to the day-to-day operation and maintenance services each will provide to Duke Power pursuant to operation and maintenance agreements related to generation facilities owned by Duke Power; (ii) disclaiming jurisdiction under Section 203 of the FPA over Duke Power's delegation to Duke Fossil and Duke Nuclear of day-to-day operation and maintenance responsibilities under the respective operation and maintenance agreements to the extent such activities may apply to FPA jurisdictional facilities under Part II of the FPA (FPA Jurisdictional Facilitates); and (iii) that Duke Fossil does not need to become a co-licensee on the hydro-electric licenses issued to Duke Power under Part I of the FPA with respect to the hydro-electric facilities owned or leased by Duke Power that Duke Fossil may operate and maintain under the operation and maintenance agreement.

Comment date: August 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211

and 385.214). All such motions or protests should be filed on or before the comment date. 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. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

David P. Boergers,

Secretary.

[FR Doc. 01–18069 Filed 7–18–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP00–40–000, –001, and –002]

Florida Gas Transmission Company; Notice of Availability of the Final Environmental Impact Statement for the Proposed FGT Phase V Expansion Project

July 13, 2001.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a final environmental impact statement (EIS) to assess the environmental impact associated with the construction of facilities proposed by Florida Gas Transmission Company (FGT) and referred to in this final EIS as the FGT Phase V Expansion Project in the above-referenced docket.

The final EIS was prepared to satisfy the requirements of the National Environmental Policy Act. The staff concludes that approval of the FGT Phase V Expansion Project, with appropriate mitigating measures as recommended, would have limited adverse environmental impact. The final EIS evaluates alternatives to the proposal, including system alternatives, route alternatives, and route variations.

The final EIS assesses the potential environmental effects of the construction and operation of the proposed facilities in Mississippi, Alabama, and Florida.

The purpose of the FGT Phase V Expansion Project is to transport up to 112,487 million cubic feet per day of natural gas on an annual basis to seven electric generation customers and others in Florida. Three of these customers, representing 94 percent of proposed transportation capacity, are in the process of developing and constructing additional gas-fired electric generating capacity to serve the growing market for electricity in Florida. FGT estimates the total cost of its Phase V Expansion Project at $452 million.

FGT proposes to construct and operate an interstate natural gas pipeline and associated aboveground facilities under Section 7(c) of the Natural Gas Act (NGA) and Title 18, CFR, Part 157. FGT proposes to expand its existing 5,225-mile-long natural gas pipeline transmission system by the construction of approximately 165.8 miles of pipeline loops and laterals, 132,615 horsepower of additional compression at nine existing and three new compressor stations, and other associated auxiliary facilities in various locations in Mississippi, Alabama, and Florida.

In addition, FGT proposes to acquire from Koch Gateway Pipeline Company (KGPC) an interest in KGPC's Mobile Bay Lateral that would give FGT the rights to about 50 percent of the available capacity on that system. Concurrent with FGT's filing, KGPC filed an application in Docket No. CP00–39–000 for approval to abandon by sale to FGT the interest in its Mobile Bay Lateral. However, the environmental analysis of this action qualifies as a categorical exclusion and is not included in the EIS.

The final EIS has been placed in the public files of the FERC and is available for public inspection at:

Federal Energy Regulatory Commission, Public Reference and Files Maintenance Branch, 888 First Street, NE., Room 2A, Washington, DC 20426, (202) 208–1371.

Copies of the final EIS have been mailed to Federal, state and local agencies, public interest groups, individuals who have requested the final EIS, newspapers, and parties to this proceeding.

In accordance with the Council on Environmental Quality's (CEQ) regulations implementing the National Environmental Policy Act, no agency decision on a proposed action may be made until 30 days after the U.S. Environmental Protection Agency publishes a notice of availability of an final EIS. However, the CEQ regulations provide an exception to this rule when an agency decision is subject to a formal internal appeal process which allows other agencies or the public to make their views known. In such cases, the agency decision may be made at the same time the notice of the final EIS is published, allowing both periods to run concurrently. The Commission decision for this proposed action is subject to a 30-day rehearing period.

Additional information about the proposed project is available from the Commission's Office of External Affairs, at (202) 208–1088 or on the FERC Internet website (www.ferc.gov) using the ''RIMS'' link to information in this docket number. Click on the ''RIMS'' link, select ''Docket #'' from the RIMS Menu, and follow the instructions. For assistance with access to RIMS, the RIMS helpline can be reached at (202) 208–2222.

Similarly, the ''CIPS'' link on the FERC Internet website provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings. From the FERC Internet website, click on the ''CIPS'' link, select ''Docket #'' from the CIPS menu, and follow the instructions. For assistance with access to CIPS, the CIPS helpline can be reached at (202) 208–2474.

David P. Boergers,

Secretary.

[FR Doc. 01–18025 Filed 7–18–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11428–000; Michigan]

Municipal Dam Hydro Project; Notice of Availability of Draft Environmental Assessment

July 13, 2001.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed the application for license for the Municipal Dam Hydroelectric Project, located on the Pine River in Gratiot County, Michigan, and has prepared a Draft Environmental Assessment (DEA) for the project.

Copies of the DEA are available for review at the Commission's Public Reference Room, located at 888 First Street, NE., Washington, DC 20426, or by calling (202) 208–1371. The DEA may be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link,

select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance).

Any comments (an original and 8 copies) should be filed within 45 days from the date of this notice and should be addressed to David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link. For further information, contact Susan O'Brien at (202) 219–2840 or *susan.obrien@ferc.fed.us.*

David P. Boergers,

Secretary.

[FR Doc. 01–18028 Filed 7–18–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Comments, Protests, and Motions To Intervene

July 13, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12054–000.

c. *Date filed:* June 18, 2001, supplemented July 10, 2001.

d. *Applicant:* David R. Croft

e. *Name of Project:* Camptonville Pow-Our House Project

f. *Location:* Would utilize the existing Our House and Log Cabin Diversion Dams and Lohman and Camptonville Tunnels of Yuba County Water Agency's Yuba River Project No. 2246, on the Middle Fork Yuba River and Oregon Creek, and would locate two new developments on Willow Creek, within the Tahoe National Forest in Yuba and Sierra Counties, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Ms. Ellen D. McCarthy, 4715 Lofty Grove, Oceanside, CA 92056, (760) 941–6618.

i. *FERC Contact:* James Hunter, (202) 219–2839.

j. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link. Please include the project number (P–12054–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing a document with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of six units of development; all of the described project works are proposed. (1) The unit at Our House Diversion Dam would consist of a 48-inch-diameter, 500-foot-long penstock connecting to the dam outlet, a powerhouse containing a 1,775-kW generating unit, and a 1.5-mile-long transmission line. (2) The unit at the Lohman Tunnel outlet would consist of a turbine placed in the outlet, a powerhouse above the outlet containing a 628-kW generating unit, and a 0.5-mile-long transmission line. (3) The unit at the Log Cabin Diversion Dam would consist of a 24-inch-diameter, 500-foot-long penstock connecting to the dam outlet, a powerhouse containing a 325-kW generating unit, and a 0.5-mile-long transmission line. (4) The unit at the Camptonville Tunnel outlet would consist of a turbine placed in the outlet, a powerhouse above the outlet containing an 800-kW generating unit, and a 1.0-mile-long transmission line. (5) The unit on Lower Willow Creek would consist of a four-foot-high concrete weir at elevation 2,300 feet, a 24-inch-diameter, 1,600-foot-long penstock connecting to a powerhouse containing a 1,810-kW generating unit, and a 1.0-mile-long transmission line. (6) The unit on Upper Willow Creek would consist of an existing 50-foot-high, 100-foot-long concrete debris dam at elevation 2,640 feet, a 18-inch-diameter, 100-foot-long penstock connecting to a powerhouse containing a 603-kW generating unit, and a 200-foot-long transmission line. The project would have an annual generation of 39.5 GWh, the market for which has not been determined.

l. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance).

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. 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.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. 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.

David P. Boergers,

Secretary.

[FR Doc. 01–18029 Filed 7–18–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Comments, Protests, and Motions To Intervene

July 13, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12060–000.

c. *Date filed:* July 2, 2001.

d. *Applicant:* Mark R. Frederick.

e. *Name of Project:* Auburn PG&E Wise Canal Power Project.

f. *Location:* Would utilize the existing Wise Canal and Rock Creek Lake of Pacific Gas & Electric Company's Drum-Spaulding Project No. 2310, in Placer County, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Mark R. Frederick, 17825 Crother Hills Road, Meadow Vista, CA 95722, (530) 887–1984.

i. *FERC Contact:* James Hunter, (202) 219–2839.

j. *Deadline for filing motions to intervene, protests, and comments:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link. Please include the project number (P–12060–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing a document with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project, using Pacific Gas & Electric Company's existing Wise Canal and Rock Creek Lake, would consist of: (1) A proposed intake structure at an existing holding pond on the canal, (2) a proposed 800-foot-long, 8-foot-diameter penstock, (3) a proposed powerhouse containing a 900-kilowatt generating unit, (4) a proposed draft tube emptying into the lake, (5) a proposed 200-foot-long transmission line, and (6) appurtenant facilities. The project would have an annual generation of 7.8 GWh that would be sold to Pacific Gas & Electric Company or a power distributor.

l. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued,

does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. 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.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. 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.

David P. Boergers,

Secretary.

[FR Doc. 01–18030 Filed 7–18–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Comments, Protests, and Motions To Intervene

July 13, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12069–000.

c. *Date filed:* July 6, 2001.

d. *Applicant:* Mark R. Frederick.

e. *Name of Project:* Rock Creek Lake Outlet Power Project.

f. *Location:* Would utilize the existing Rock Creek Lake and Wise Canal of Pacific Gas & Electric Company's Drum-Spaulding Project No. 2310, in Placer County, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Mark R. Frederick, 17825 Crother Hills Road, Meadow Vista, CA 95722, (530) 887–1984.

i. *FERC Contact:* James Hunter, (202) 219–2839.

j. *Deadline for filing motions to intervene, protests, and comments:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link. Please include the project number (P–12069–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing a document with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. Description of Project: The proposed project, using Pacific Gas & Electric Company's existing Rock Creek Lake and Wise Canal, would consist of: (1) a proposed gated intake attached to the existing outfall conduit from the lake, (2) a proposed 100-foot-long, 6-foot-diameter penstock, (3) a proposed powerhouse containing a 600-kilowatt generating unit, (4) a proposed tailrace emptying into the canal, (5) a proposed connection to an overhead transmission line, and (6) appurtenant facilities. The project would have an annual generation of 5.2 GWh that would be sold to Pacific Gas & Electric Company or a power distributor.

l. Copies of this filing are on file with the Commission and are available for public inspection. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include

an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. 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.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. 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.

David P. Boergers,

Secretary.

[FR Doc. 01–18031 Filed 7–18–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Regulations Governing Off-the-Record Communications; Public Notice

July 13, 2001.

This constitutes notice, in accordance with 18 CFR 385.2201(h), of the receipt of exempt and prohibited off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive an exempt or a prohibited off-the-record communication relevant to the merits of a contested on-the-record proceeding, to deliver a copy of the communication, if written, or a summary of the substance of any oral communication, to the Secretary.

Prohibited communications will be included in a public, non-decisional file associated with, but not part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such requests only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication should serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications will be included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of exempt and prohibited off-the-record communications received in the Office of the Secretary within the preceding 14 days. The documents may be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Exempt

1. Project No. 2835–005; 07–03–01; Jack Hannula.
2. Project No. 2016; 07–05–01; Allyson Brooks.
3. CP00–412–000; 07–12–01; David Swearingen.
4. Project No. 2055; 07–11–01; John Sullivan.
5. DO01–2–000; 07–13–01; Dean Schnitzler.

David P. Boergers,

Secretary.

[FR Doc. 01–18024 Filed 7–18–01; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7014–7]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Compliance Assistance Surveys for the Marina, Metal Finishing, Construction Site, and Auto Salvage Yard Sectors

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Compliance Assistance Surveys for the Marina, Metal Finishing, Construction Site, and Auto Salvage Yard Sectors (EPA ICR Number 2021.01). The ICR describes the nature of the information collection and its expected burden and cost; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 20, 2001.

ADDRESSES: Send comments, referencing EPA ICR No. 2021.01 to the following addresses: Sandy Farmer, U.S.

Environmental Protection Agency, Collection Strategies Division (Mail Code 2822), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; and to Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: For a copy of the ICR contact Sandy Farmer at EPA by phone at (202) 260–2740, by E-mail at Farmer.Sandy@epamail.epa.gov, or download off the Internet at http://www.epa.gov/icr and refer to EPA ICR No. 2021.01. For technical questions about the ICR contact Lynn Vendinello on (202) 564–7066.

SUPPLEMENTARY INFORMATION:

Title: Compliance Assistance Surveys for the Marina, Metal Finishing, Construction Site, and Auto Salvage Yard Sectors (EPA ICR Number 2021.01). This is a new collection.

Abstract: EPA's Office of Compliance (OC) is interested in testing methods for collecting outcome data from their compliance assistance efforts. OC is planning to conduct surveys to three sectors to compare two survey methodologies: mailed surveys using the ''total design method'' and surveys conducted as on-site visits. EPA will also use the survey results to evaluate the impact of compliance assistance activities on facilities in these sectors. These surveys will support OC in collecting statistically valid compliance assistance outcome data needed to present the impacts of compliance assistance for Government Performance and Results Act (GPRA) reporting purposes. OC is interested in conducting the surveys for sectors in three stages of analysis/activity: (1) A sector for which OC is beginning a compliance assistance effort (marinas); (2) a sector for which OC/EPA have conducted several compliance assistance activities (metal finishing); and (3) a sector for which OC doesn't have sufficient information to determine compliance assistance needs (either construction sites or auto salvage yards).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The **Federal Register** document required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on March 23, 2001 (66 FR 16223). EPA received two written comments; one from the Automotive Recyclers Association and the other from the Institute of Scrap Recycling Industries. EPA also met with and received comment from Christian Richter of The Policy Group which represents the Association of Electroplaters and Surface Finishers, National Association of Metal Finishers, and Metal Finishers Suppliers Association.

Burden Statement: The annual public reporting and record keeping burden for this collection of information is estimated to average 1 hour per response for the mailed surveys in each sector and 4 hours per response for the site visit surveys in each sector. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Marina, Metal Finishing, Construction Site, and Auto Salvage Yard Sectors.

Estimated Number of Respondents: 700.

Frequency of Response: Once.

Estimated Total Annual Hour Burden: 1,900 hours.

Estimated Total Annualized Capital, Operating/Maintenance Cost Burden: 0.

Send 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 through the use of automated collection techniques to the addresses listed above. Please refer to EPA ICR No. 2021.01 in any correspondence.

Dated: July 10, 2001.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 01–18096 Filed 7–18–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7013–2]

Proposed Settlement Agreement, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement agreement; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''Act''), 42 U.S.C. 7413(g), notice is hereby given of a proposed Settlement Agreement, which was filed with the United States Court of Appeals for the District of Columbia Circuit by the United States Environmental Protection Agency (''EPA'') on June 29, 2001, to address a lawsuit filed by the Clean Air Implementation Project and the National Environmental Development Association's Clean Air Regulatory Project (collectively referred to as the ''Project''). The Project filed a petition for review pursuant to section 307(b) of the Act, 42 U.S.C. 7607(b), challenging EPA's policy, ''State Implementation Plans: Policy Regarding Excess Emissions During Malfunction, Startup and Shutdown,'' (''1999 Policy''), which is dated September 20, 1999. *Clean Air Implementation Project* v. *EPA,* No. 99–1470 (D.C. Cir.). The 1999 Policy clarifies the types of provisions addressing emissions in excess of applicable emission limits that EPA believes may appropriately be approved as part of a state implementation plan (''SIP'').

DATES: Written comments on the proposed Settlement Agreement must be received by August 20, 2001.

ADDRESSES: Written comments should be sent to Jan M. Tierney, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC. 20460. Copies of the proposed Settlement Agreement are available from Phyllis J. Cochran, (202) 564–5566. A copy of the proposed Settlement Agreement was filed with the Clerk of the United States Court of Appeals for the District of Columbia Circuit on June 29, 2001.

SUPPLEMENTARY INFORMATION: The Project alleges that EPA's issuance of the 1999 Policy was arbitrary and capricious and in excess of EPA's statutory authority. EPA issued the 1999 Policy to clarify issues that had arisen since the Agency's pronouncement on the same issues in 1982 and 1983 in two memoranda issued by Kathleen Bennett, who at that time was the Assistant

Administrator for Air, Noise and Radiation.

The proposed Settlement Agreement provides for the Project to dismiss its challenge if EPA issues a brief memorandum clarifying certain issues in the 1999 Policy and if that brief memorandum is substantially similar to what is set forth as Attachment A to the proposed Settlement Agreement. In general, the brief memorandum would provide that the 1999 Policy was intended to provide the parameters for EPA review of future SIP submissions and was not intended to be legally dispositive when interpreting existing approved SIPs in the context of enforcement proceedings.

For a period of thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the proposed Settlement Agreement from persons who were not named as parties or interveners to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed Settlement Agreement if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determine, following the comment period, that consent is inappropriate, the proposed Settlement Agreement will be final.

Dated: July 9, 2001.

John T. Hannon,

Acting Associate General Counsel.

[FR Doc. 01–17908 Filed 7–18–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7014–6]

Notice of Public Meetings; Extension of Intel Project XL

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces that Intel and EPA plan to continue their innovative partnership under the Excellence and Leadership Program (XL) through renewal of an existing agreement. Because the Intel XL Project is based on strong stakeholder involvement, Intel and EPA are announcing a series of public meetings at which extension of the Intel XL Project will be discussed. Intel and EPA are inviting public participation at those meetings for those people interested in the Intel XL Project, or the XL Program in general. Public participation is also encouraged via the internet.

DATES AND ADDRESSES: All public meetings will be held at the Chandler Public Library, City Council Chamber, 2nd Floor, 222 E. Commonwealth Ave., Chandler, Arizona at 6:30 p.m. Meetings will be held on the following dates:
July 24, 2001
August 21, 2001
September 18, 2001
October 16, 2001
November 13, 2001

FOR FURTHER INFORMATION CONTACT: Colleen McKaughan, Associate Director, Air Division (AIR–1), U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, California 94105; Telephone: (520) 498–0118; Email:mckaughan.colleen@epa.gov.

SUPPLEMENTARY INFORMATION: In March of 1995, EPA announced a new environmental program called Project XL, or Excellence and Leadership. The purpose of this program is to work with interested companies, state and local agencies, and communities to develop innovative approaches for addressing environmental issues. Among the qualifications for an XL Project, a company's innovative ideas must provide better environmental performance compared to compliance with both current and future regulations, produce cost savings, and significantly involve the community.

Intel Corporation was an early volunteer for this program and sponsor of one of the first eight projects selected by EPA in November 1995. Intel convened a stakeholder team made up of representatives of EPA, the Gila River Indian Community, the State of Arizona, Maricopa County, the City of Chandler, and four members of the public. The stakeholder team developed a project that provided operational flexibility for Intel while providing greater environmental protection to the community. The details of the project are spelled out in the Final Project Agreement (FPA) dated November 19, 1996 (available on EPA's website at *http://www.epa.gov/ProjectXL/intel/index.htm* and Intel's website at *http://www.intel.com/intel/other/ehs/projectxl*). The FPA was signed by the stakeholders, and has been implemented successfully as a pilot project over the last 5 years.

Intel and EPA would like to extend the Intel XL Project for another 5 years, based on the successful pilot program. This extension is also supported by the stakeholders, most of whom have participated in the project's implementation over the past 5 years. In order to extend the project, the FPA and Intel's operating permit need to be renewed. Intel and EPA would like to invite the public to participate in the discussions related to these renewals.

There are several ways to participate. People can attend the meetings which are listed in this notice, or they can participate through the internet. Comments can be posted to the Intel website at http://www.alt-path.com/ocotillo. If you wish to speak to someone in person regarding participating in this effort, you may also contact Colleen McKaughan of EPA at: 520–498–0118 or mckaughan.colleen@epa.gov.

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

Dated: July 12, 2001.

Elizabeth A. Shaw,

Director, Office of Environmental Policy Innovation.

[FR Doc. 01–18095 Filed 7–18–01; 8:45 am]

BILLING CODE 6560–50–U

EVIRONMENTAL PROTECTION AGENCY

[OPP–34225G; FRL–6791–9]

Diazinon; Products Cancellation Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's cancellation order for the product and use cancellations as requested by three companies (Drexel Chemical Co., Aventis Environmental Science and Gowan Co., hereafter collectively referred to as the ''MUP Registrants'') that hold the registrations of pesticide manufacturing-use and end-use products (MUPs and EUPs) containing the active ingredient diazinon and accepted by EPA, pursuant to section 6(f) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This order follows up a May 30, 2001, notice of receipt of the three companies' requests for cancellations and amendments of their diazinon product registrations to terminate all indoor uses and certain agricultural uses. In the May 30, 2001 notice, EPA indicated that it would issue an order confirming the voluntary product and use registration cancellations unless the Agency received any substantive comment within the comment period that would merit its further review of these requests. The Agency received comments on outdoor non-agricultural uses. This notice addresses these comments, which do not effect the

Agency's decision to grant the MUP registrant's request. Any distribution, sale, or use of the products subject to this cancellation order is only permitted in accordance with the terms of the existing stocks provisions of this cancellation order. This notice also announces EPA's amendment to a cancellation order that was issued on April 24, 2001 and published in the **Federal Register** on May 2, 2001. The order is amended to include an existing stock provisions for products bearing instructions for any of the canceled agricultural uses.

DATES: The cancellations are effective July 19, 2001.

FOR FURTHER INFORMATION CONTACT: By mail: Ben Chambliss, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, telephone number: (703) 308–8174; fax number: (703) 308–7042; e-mail address: chambliss.ben@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. You may be potentially affected by this action if you manufacture, sell, distribute, or use diazinon products. The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule, for purposes of 5 U.S.C. 804(3). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the **Federal Register**—Environmental Documents. You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access information about the risk assessment for diazinon, go to the Home Page for the Office of Pesticide Programs or go directly to http://www.epa.gov/pesticides/op/diazinon.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–34225G. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Receipt of Requests to Cancel and Amend Registrations to Delete Uses

A. Background

In separate letters dated February 20, 2001, for Aventis Environmental Science, March 6, 2001, for Drexel Chemical Company and April 26, 2001, for Gowan Company, manufacturers of MUPs and registrants of EUPs containing diazinon, requested cancellation of all indoor and certain agricultural uses from their diazinon products to reduce the potential exposure to children associated with diazinon containing products. The letters, with the exception of the letter from Aventis, also requested that EPA cancel their registrations for the manufacturing-use pesticide products containing diazinon, conditioned upon issuance of replacement registrations which do not allow their use in formulation of end-use products for the deleted uses, and which includes expiration of the registration for outdoor non-agricultural uses. The letter from Aventis Environmental Science, requested cancellation of its MUPs without issuance of replacement registrations. EPA has acted on the requests and issued new registrations in March and May 2001. In addition, these companies have asked EPA to cancel or amend their registrations for end-use products containing diazinon consistent with the use cancellation request. The uses for which termination was requested are identified in the following List 1.

List 1. — Uses Requested for Termination

Indoor uses. Pet collars, or inside any structure or vehicle, vessel, or aircraft or any enclosed area, and/or on any contents therein (except mushroom houses), including food/feed handling establishments. greenhouses, schools, residences, museums, sports facilities, stores, warehouses, and hospitals.

Agricultural uses. Alfalfa, bananas, Bermuda grass, dried beans, dried peas, celery, red chicory (radicchio), citrus, clover, coffee, cotton, cowpeas, cucumbers, dandelions, forestry (ground squirrel/rodent burrow dust stations for public health use), kiwi, lespedeza, parsley, parsnips, pastures, peppers, potatoes (Irish and sweet), sheep, sorghum, squash (winter and summer), rangeland, Swiss chard, tobacco, and turnips.

Pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA announced the Agency's receipt of these requests from the MUP registrants by a **Federal Register** notice published on May 30, 2001 (66 FR 29310) (FRL–6785–2). In that notice, EPA provided a 30–day comment period. The registrants requested that the Administrator waive the 180–day comment period provided under FIFRA section 6(f)(1)(C). EPA also approved the replacement registrations for the registrants' diazinon manufacturing-use products in March and May 2001.

Before the May 30th publication of the 6(f) notice announcing the diazinon product and use cancellation requests, EPA received many comments from growers, as well as the U.S. Department of Agriculture, expressing that the use of diazinon pesticide products is vital for many of the agricultural uses identified in List 1 of this notice. According to the comments, there is a nationwide need for the application of diazinon products on spinach, strawberries, and tomatoes.

There are also needs for the application of diazinon products on certain crops in certain states. These needs are identified in the following Table 1.

TABLE 1. — SPECIFIC REGIONAL NEED FOR DIAZINON END-USE PRODUCTS

Crop	Use Area(s)
Bananas	Hawaii
Celery	Texas

TABLE 1. — SPECIFIC REGIONAL NEED FOR DIAZINON END-USE PRODUCTS—Continued

Crop	Use Area(s)
Cucumbers	Texas
Ground squirrel/ rodent burrow dust stations for public health use	California
Parsley	Texas and California
Parsnips	Texas and Oregon
Peas, succulent	Texas and Maryland
Peppers	Texas and California
Potatoes, Irish	Texas, Washington and Michigan
Potatoes, sweet	Texas
Squash, summer and winter	Texas and California
Swiss Chard	Texas
Turnips, root	Texas and Oregon
Turnips, tops	Texas and Oregon

In response to these comments, the MUP Registrants agreed to maintain on their diazinon product registrations the use on spinach, strawberries and tomatoes. EPA's assessment of risks associated with the use of diazinon products concluded that all acute and chronic dietary risk estimates are below the Agency's level of concern. EPA's assessment considered all currently registered uses, including the agricultural uses identified in List 1. There may also be adequate data to support the tolerances for spinach, strawberries and tomatoes. EPA is currently reviewing residue data for these crops recently provided by the registrant to determine their acceptability. Accordingly, pursuant to FIFRA section 3(c)(7)(A), EPA approved the amendments of the MUP Registrants' replacement manufacturing-use product registrations to permit formulation and reformulation into products bearing instructions for spinach, strawberries and tomatoes. As amended, the approved replacement registrations for the MUP Registrants diazinon manufacturing-use products permit formulation and reformulation into products bearing instructions only for the agricultural uses identified in the following List 2.

List 2. — Agricultural Uses in Technical Registrants' Replacement Manufacturing-Use Product Registrations

Almonds, apples, apricots, beans (seed treatment only) except soybeans, beets, blackberries, blueberries, boysenberries, broccoli, cattle (non-lactating; ear tags only), Chinese broccoli, Brussels sprouts, cabbage, Chinese cabbage (bok choy and napa), cantaloupes, carrots, Casaba melons, cauliflower, cherries, collards, field corn (seed treatment only), sweet corn (including seed treatment), cranberries, Crenshaw melons, dewberries, endive (escarole), ginseng, grapes, honeydew melons, hops, kale, lettuce, lima beans (seed treatment only), loganberries, melons, muskmelons, mustard greens, Chinese mustard, nectarines, onions, peaches, pears, peas (seed treatment only), Persian melons, pineapples, plums, prunes, radishes, Chinese radishes, raspberries, rutabagas, spinach, strawberries, sugar beets, tomatoes, walnuts, watercress (Hawaii only), and watermelons.

Similarly, in today's cancellation order, EPA is approving the registrants' requested cancellations and amendments of the diazinon end-use products registrations, to terminate all uses identified in List 1 except spinach, strawberries and tomatoes. The individual states identified in Table 1 of this notice, may wish to issue special-local-need registrations under FIFRA section 24(c) for diazinon end-use products to address the specific agricultural needs in their states respectively, as identified in Table 1.

EPA also received two comments asking that EPA cancel the outdoor non-agricultural uses of diazinon products now rather than in 2004. In assessing outdoor non-agricultural uses of diazinon products, EPA has considered many factors, including:

1. The risks and the benefits associated with such uses.
2. The phasing out over the next 3 years of the production of diazinon technical products that can be formulated or reformulated into products labeled for outdoor non-agricultural uses.
3. The possibility of and potential impacts from any litigation that may result from a proceeding by EPA to cancel these uses.

Based on its consideration of all of these factors, EPA currently is not contemplating initiating a regulatory proceeding to cancel these uses.

B. Requests for Voluntary Cancellation of Manufacturing Use Products

Pursuant to FIFRA section 6(f)(1)(A), the registrants submitted requests for voluntary cancellation of the registrations for their diazinon manufacturing-use products, conditioned upon EPA's issuance of replacement registrations for these products which do not allow their formulation or reformulation into products bearing instructions for indoor use or certain agricultural uses, as identified in List 1 of this notice. The product registrations for which cancellations were requested are identified in the following Table 2.

TABLE 2. — MANUFACTURING-USE PRODUCT REGISTRATION CANCELLATION REQUESTS

Company	Reg. No.	Product
Aventis Environmental Science	432–1094	Pyrenone Diazinon
Aqueous Base Science	432–1130	Pyrenone Diazinon S.E.C.
Gowan Company	10163–212	Gowan Diazinon Technical
Drexel Chemical Co.	19713–104	Diazinon Technical

As mentioned in Unit II.A of this notice, EPA received comments requesting that the Agency continues to permit the use of diazinon products on certain agricultural sites that the MUP Registrants had proposed to cancel. In response to these comments, pursuant to FIFRA section 3(c)(7)(A), EPA approved the MUP Registrants' amendments of the replacement registrations for their diazinon manufacturing-use products to permit formulation and reformulation of these replacement manufacturing use products into products bearing instructions for spinach, strawberries, and tomatoes, because there appears to be a nationwide need for the use of diazinon products on these crops. The individual states identified in Table 1 above, may wish to issue special-local-need registrations under FIFRA section 24(c) for diazinon end-use products to meet the specific agricultural needs in their states, as identified in Table 1. Because the concerns expressed in the comments have been addressed, EPA is issuing an order in this notice canceling the registrations identified in Table 2, as requested by the MUP Registrants.

C. Requests for Voluntary Cancellation of End-Use Products

In addition to requesting voluntary cancellation of its diazinon manufacturing-use product registrations, Syngenta also submitted requests for voluntary cancellation of the registrations for its diazinon end-use products that are registered primarily for indoor use. These end-use product registrations for which cancellation was requested are identified in the following Table 3.

TABLE 3. — END-USE PRODUCT REGISTRATION CANCELLATION REQUESTS

Company	Reg. No.	Product
Syngenta Crop Protection, Inc.	100–463	D.Z.N. DIAZINON 4E Insecticide
	100–785	Evict Indoor/Outdoor WBC
Aventis Environmental Science	432–907	Ford's Diazinon 4E Insecticide
	432–979	Pyrenone Diazinon Residual Concentrate Insecticide
	432–987	Pyrenone Diazinon Residual Spray Insecticide
	432–1062	Roach and Ant Spray Aqueous
	432–1108	Pyrenone Diazinon W.B.
	432–1114	Pyrenone Diazinon Water Based Pressurized Spray
	432–1119	Pyrenone Diazinon Water Based Pressurized Spray II

EPA did not receive any comments expressing a need for diazinon products for indoor use. Accordingly, EPA is issuing an order in this notice canceling the registrations identified in Table 3, as requested by Syngenta and Aventis.

D. Requests for Voluntary Amendments of End-Use Product Registrations to Terminate Certain Uses

Pursuant to section 6(f)(1)(A) of FIFRA, the Technical Registrants submitted requests to amend a number of their diazinon end-use product registrations to terminate the uses identified in List 1 of this notice. The registrations for which amendments to terminate uses were requested are identified in the following Table 4.

TABLE 4. — END-USE PRODUCT REGISTRATIONS REQUESTS FOR AMENDMENTS TO TERMINATE USES

Company	Reg. No.	Product
Drexel Chemical Co	19713–91	Diazinon Insecticide
	19713–92	D–264 4E Diazinon Insecticide
	19713–95	D–264 14G
	19713–145	D–264 Captan Seed Protection
	19713–263	DIAZINON 5G
	19713–264	DIAZINON 2G
	19713–317	Bug Spray (SP)
	19713–492	Diazinon 50 WP

As mentioned in Unit II.A of this notice, EPA received comments requesting that the Agency continue to permit the use of diazinon products on certain agricultural sites that the Technical Registrants had proposed to cancel. In response to these comments, the Technical Registrants have agreed to retain the use on spinach, strawberries, and tomatoes on their current diazinon end-use product registrations. The individual states identified in Table 1, may also wish to issue special-local-need registrations under FIFRA section 24(c) for diazinon end-use products to meet the specific agricultural needs in their states, as identified in Table 1. Accordingly, EPA is issuing an order in this notice approving the amendments of the registrations identified in Table 4 to terminate all uses identified in List 1 except spinach, strawberries, and tomatoes.

III. Cancellation Order

Pursuant to section 6(f) of FIFRA, EPA hereby approves the requested diazinon product registration cancellations and amendments to terminate all indoor uses and certain agricultural uses, as identified in List 1 of this notice, except spinach, strawberries, and tomatoes. Accordingly, the Agency orders that the diazinon manufacturing use product registrations identified in Table 2 of this notice, and the diazinon end-use product registrations identified in Table 3 of this notice, are hereby canceled. The Agency also orders that all of the uses identified in List 1, except spinach, strawberries, and tomatoes, are hereby canceled from all end-use product registrations identified in Table 4. Any distribution, sale, or use of existing stocks of the products identified in Tables 2–4 in a manner inconsistent with the terms of this order or the existing stock provisions in Unit IV of this notice will be considered a violation of section 12(a)(2)(K) of FIFRA and/or section 12(a)(1)(A) of FIFRA.

IV. Existing Stocks Provisions

For purposes of this Order, the term ''existing stocks'' is defined, pursuant to EPA's existing stocks policy (56 FR 29362, June 26, 1991), as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the amendment or cancellation. The existing stocks provisions of this cancellation order are as follows:

1. *Distribution or sale of manufacturing-use products.* Distribution or sale by any person of the existing stocks of any product identified in Table 2 of this notice, will not be lawful under FIFRA after July 19, 2001, except for the purpose of returns for relabeling consistent with the Technical Registrants' cancellation request letters and the memorandum of agreement (MOA), shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or proper disposal.

2. *Use of manufacturing-use products to formulate for indoor use.* Use by any person of the existing stocks of any product identified in Table 2 of this notice, for formulation or reformulation into any product that bears instructions for indoor use will not be lawful under FIFRA after July 19, 2001. All other uses of such products may continue until the existing stocks are exhausted, provided that such use does not violate any existing stocks provision of this cancellation order and is in accordance with the existing labeling of that product.

3. *Use of manufacturing-use products to formulate for agricultural use.* Use by any person of the existing stocks of any product identified in Table 2 of this notice, for formulation or reformulation into any product bearing instructions for the agricultural uses identified in List 1 of this notice, except spinach, strawberries and tomatoes, will not be lawful under FIFRA after the date of publication of this **Federal Register** notice. All other uses of such products may continue until the existing stocks are exhausted, provided that such use does not violate any existing stocks provision of this cancellation order and is in accordance with the existing labeling of that product.

4. *Sale or distribution of indoor end-use products by MUP registrants.* Sale or distribution by the MUP registrants of the existing stocks of any product identified in Table 3 or Table 4 of this notice that bear instructions for indoor use will not be lawful under FIFRA after July 19, 2001, except for the purposes of returns for relabeling consistent with the Technical Registrants' cancellation request letters and the MOA, shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or proper disposal.

5. *Retail and other sale or distribution of indoor end-use products.* Sale or distribution by any person of the existing stocks of any product identified in Table 3 or Table 4 of this notice that bear instructions for indoor use will not be lawful under FIFRA after December 31, 2002, except for the purpose of returns for relabeling consistent with the Technical Registrants' cancellation request letters and the MOA, shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or proper disposal.

6. *Distribution or sale of diazinon end-use products bearing directions for use on agricultural crops.* Sale and distribution by the registrant of end-use products bearing directions for use on any of the canceled agricultural crops will be unlawful 1–year after the effective date of this cancellation order. Persons other than the registrant may continue to sell existing stocks after the effective date of the cancellation order.

V. Amendment to April 24, 2001 Cancellation Order (66 FR 21967 (May 2, 2001))

Pursuant to sections 6(f) and 6(a)(1) of FIFRA, EPA hereby amends its cancellation order that was issued on April 24, 2001 and published in the May 2, 2001 issue of the **Federal Register**. The order is hereby amended to include in section IV of the order the following existing stocks provision.

Distribution and sale of end-use products bearing instructions for use on agricultural crops. The distribution or sale of the existing stocks by the registrant of any product listed in Table 3 or 4 that bears instructions for any of the agricultural uses identified in List 1, except spinach, strawberries and tomatoes, will not be lawful under FIFRA 1–year after the effective date of the cancellation order. Persons other than the registrants may continue to sell or distribute the existing stocks listed in Table 3 or 4 that bears instructions for any of the agricultural uses identified in List 1 after the effective date of the cancellation order.

List of Subjects

Environmental protection, Memorandum of Agreement, Pesticides and pests.

Dated: July 3, 2001.

Lois Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 01–18097 Filed 7–18–01; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1033; FRL–6793–9]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1033, must be received on or before August 20, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1033 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Dan Peacock, Insecticide-Rodenticide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5407; e-mail address: peacock.dan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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 the table 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. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations.'' ''Regulation and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–1033. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall

#2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1033 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1033. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated:July 2, 2001

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summaries of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Syngenta Crop Protection, Inc.

PP 8F4984, 8F5031, 0F6141

EPA has received pesticide petitions (8F4984, 8F5031, 0F6141) from Syngenta Crop Protection, Inc., PO Box 18300 Greensboro, NC 27419–8300 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of pymetrozine in or on the raw agricultural commodities cotton gin byproducts at 3.0 parts per million (ppm), cottonseed at 0.4 ppm, cucurbit vegetables at 0.1 ppm, hops at 5.0 ppm, fruiting vegetables at 0.2 ppm, leafy vegetables (except Brassica) at 6.0 ppm, head and stem Brassica vegetables at 2.0 ppm, leafy Brassica greens at 5.0 ppm and pecans at 0.02 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of pymetrozine in plants is understood for the purposes of the proposed tolerances. Studies in rice, tomatoes, cotton and potatoes gave similar results. The metabolic pathways have demonstrated that pymetrozine, per se, is the residue of concern for tolerance setting purposes.

2. *Analytical method*. Syngenta has submitted an analytical method (AG–643) for the determination of pymetrozine in crop substrates. The limit of detection (LOD) for the analytical method is 1.0 ng and the limit of quantification (LOQ) is 0.02 ppm. Samples are extracted, purified with solid-phase and liquid-liquid partitions and analyzed by high performance liquid chromotography (HPLC). Analytical method has undergone independent laboratory validation. The

pymetrozine Analytical Method AG–643 is proposed as the tolerance enforcement method. Syngenta has also submitted an analytical method (AG–647) for the determination of the major crop metabolite of pymetrozine, GS–23199. GS–23199 is considered a marker for metabolite residues. This metabolite is not proposed as part of the tolerance expression. Samples are extracted, purified with solid-phase and/or liquid-liquid partitions and analyzed by HPLC.

3. *Magnitude of residues*. Residue data were generated for pymetrozine for tolerance setting and dietary exposure estimates. Data were also generated for a major metabolite, GS–23199. Adequate residue trials were performed for pymetrozine on the uses proposed in this notice of filing.

B. Toxicological Profile

1. *Acute toxicity*. Pymetrozine has low acute toxicity. The oral LD_{50} in rats is > 5,820 milligrams/kilogram(mg/kg) for males and females, combined. The rat dermal LD_{50} is > 2,000 mg/kg and the rat inhalation LC_{50} is > 1.8 milligrams/liter(mg/L) air. Pymetrozine is not a skin sensitizer in guinea pigs and does not produce dermal irritation in rabbits. It produces minimal eye irritation in rabbits. End-use water-dispersible granule formulations of pymetrozine have similar low acute toxicity profiles.

2. *Genotoxicity*. Pymetrozine did not induce point mutations in bacteria (Ames assay in *Salmonella typhimurium* and *Escherichia coli*) or in cultured mammalian cells (Chinese hamster V79) and was not genotoxic in an *in vitro* unscheduled DNA synthesis assay in rat hepatocytes. Chromosome aberrations were not observed in an *in vitro* test using Chinese hamster ovary cells and there were no clastogenic or aneugenic effects on mouse bone marrow cells in an *in vivo* mouse micronucleus test. These studies show that pymetrozine is not mutagenic or genotoxic.

3. *Reproductive and developmental toxicity*. In a teratology study in rats, pymetrozine caused decreased body weights and food consumption in females given 100 and 300 mg/kg/day during gestation. This maternal toxicity was accompanied by fetal skeletal anomalies and variations consistent with delayed ossification. The no-observed-adverse-effect level (NOAEL) for maternal and fetal effects in rats was 30 mg/kg/day. In a rabbit teratology study, maternal death, reduced body weight gain and food consumption were observed at 125 mg/kg/day (highest dose tested). Embryo- and feto-toxicity (abortion in one female and total resorptions in two females) accompanied maternal toxicity. Body weight and food consumption decreases, early resorptions and postimplantation losses were also observed in maternal rabbits given 75 mg/kg/day. There was an increased incidence of fetal skeletal anomalies and variations at these maternally toxic doses. The NOAEL for maternal and fetal effects in rabbits was 10 mg/kg/day. Pymetrozine is not teratogenic in rats or rabbits. In a two generation reproduction study in rats, parental body weights and food consumption were decreased, liver and spleen weights were reduced and histopathological changes in liver, spleen and pituitary were observed at approximately 110–440 mg/kg/day (highest dose tested). Liver hypertrophy was observed in a few parental males at approximately 10–40 mg/kg/day. Reproductive parameters were not affected by treatment with pymetrozine. The NOAEL for reproductive toxicity is approximately 110–440 mg/kg/day. The NOAEL for toxicity to adults and pups is approximately 1–4 mg/kg/day.

4. *Subchronic toxicity*. Pymetrozine was evaluated in 13–week subchronic toxicity studies in rats, dogs and mice. Liver, kidneys, thymus and spleen were identified as target organs. The NOAEL was 33 mg/kg/day in rats and 3 mg/kg/day in dogs. In mice, increased liver weights and microscopical changes in the liver were observed at all doses tested. The NOAEL in mice was <198 mg/kg/day. No dermal irritation or systemic toxicity occurred in a 28–day repeated dose dermal toxicity study with pymetrozine in rats given 1,000 mg/kg/day. Minimum direct dermal absorption (1.1%) of pymetrozine was detected in rats over a 21 hour period of dermal exposure. Maximum radioactivity left on or in the skin at the application site and considered for potential absorption was 11.9%.

5. *Chronic toxicity*. Based on chronic toxicity studies in the dog and rat, a reference dose (RfD) of 0.0057 mg/kg/day is proposed for pymetrozine. This RfD is based on a NOAEL of 0.57 mg/kg/day established in the chronic dog study and an uncertainty factor of 100 to account for interspecies extrapolation and interspecies variability. Minor changes in blood chemistry parameters, including higher plasma cholesterol and phospholipid levels, were observed in the dog at the lowest-observed-adverse-effect level (LOAEL) of 5.3 mg/kg/day. The NOAEL established in the rat chronic toxicity study was 3.7 mg/kg/day and was based on reduced body weight gain and food consumption, hematology and blood chemistry changes, liver pathology and biliary cysts.

The carcinogenic potential of pymetrozine has been evaluated in rats and mice. A liver tumor response was observed in male and female mice and female rats at high doses exceeding the maximum tolerated dose. These liver tumors correlated with reversible biochemical (induction of liver metabolizing enzymes) and morphological (hepatocyte and smooth endoplasmic reticulum proliferation) changes and a reversible saturation of metabolic processes. EPA has assigned a cancer classification of ''likely'' to pymetrozine and calculated a Q1* value. However, Syngenta believes that the mechanism of action leading to liver tumors at maximum tolerated doses is a non-genotoxic threshold event and should be regulated as such.

6. *Animal metabolism*. The metabolism of pymetrozine in the rat is well understood. Metabolism involves oxidation of substituent groups of the triazine ring yielding ketones and carboxylic acids. Hydrolysis of the enamino bridge between rings results in products that are further metabolized. The metabolic pathways in animals and plants are similar.

7. *Metabolite toxicology*. The residue of concern for tolerance setting purposes is the parent compound. Metabolites of pymetrozine are considered to be of equal or lesser toxicity than the parent.

8. *Endocrine disruption*. Pymetrozine does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. There is no evidence that pymetrozine has any effect on endocrine function in developmental and reproduction studies. Furthermore, histological investigation of endocrine organs in chronic dog, rat and mouse studies did not indicate that the endocrine system is targeted by pymetrozine.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. A tier 3 chronic analysis was conducted for pymetrozine using average (mean) field trial residues for the following crops and crop groups: cotton, pecans, hops, cucurbits, fruiting vegetables, tuberous and corm, Brassica leafy vegetables and leafy vegetables. The average field trial values were adjusted for the percent of crop-treated and residue values for processed commodities were calculated by applying processing factors (either default or empirically-derived) to average field trial values of the raw agricultural commodity. Secondary residues in animal commodities were not included in the exposure assessment since a three-level dairy feeding study

in lactating livestock showed no residues at any of the feeding levels and the highest feeding level (10 ppm) was at least 10–fold higher than what would be expected in treated feed. Exposure was evaluated using the Dietary Exposure Evaluation Model (DEEM®) and food consumption information from USDA's 1994–96 Continuing Survey of Food Intake by Individuals (CSFII). Dietary exposure for the general population was 0.5% of the chronic reference dose (cRfD) of 0.0038 mg/kg/day based on a no-observed-adverse-effect level (NOAEL) of 0.38 mg/kg/day from a chronic feeding study in rats and a 100X uncertainty factor. Exposure to the U.S. population for each season, each region and for all ethnic groups in the DEEM® were also compared to the cRfD of 0.0038 mg/kg/day and ranged from 0.4–0.9%. Exposure to all male subpopulations and seniors (55+ years old) ranged between 0.4–0.5% of the cRfD (0.0038 mg/kg/day). Chronic dietary exposure to females, infants and children was compared to a chronic population adjusted dose (cPAD) of 0.0013 mg/kg/day based on the NOAEL of 0.38 mg/kg/day (described above) and a 300X uncertainty factor. The chronic dietary exposure results for the most sensitive female population subgroup, females (13+ years and nursing), was 2.2% of the cPAD. The most sensitive population containing children exclusively was children (1–6 years old) with an exposure of 2.5% of the cPAD. Lifetime cancer risk to pymetrozine was evaluated by comparing exposure to a Q* value of 0.0119. The assessment was conducted as for the chronic assessment described above. Lifetime risk for the U.S. population was 2.24×10^{-7}. The most sensitive adult population was females (13+, nursing) with a lifetime risk of 3.46×10^{-7}. These exposure estimates are conservative since field trial residues were utilized and do not reflect residue reductions expected in normal food commerce, storage or food preparation. Therefore, these results show that there is more than a reasonable certainty of no harm resulting from chronic exposure through the consumption of pymetrozine-treated commodities.

A tier 3 probabilistic acute dietary analysis was conducted with a full distribution of residues for each commodity described above. Each residue distribution was adjusted for percent of crop treated by adding zeroes to the distribution to account for the percent of crop not treated. This acute assessment was conducted using the DEEM® software and food consumption information from USDA's 1994–96 CSFII. Processing factors were used to adjust average field trial values for processed (blended) commodities and were obtained either empirically or from default values. EPA has required that exposure to females (13+ years old) be compared to a NOAEL of 10 mg/kg/day based on a rabbit developmental study and a 300X uncertainty factor. Acute exposure to the most sensitive female subpopulation, females (13–50 years old), was 1.61% of the acute population adjusted-dose (aPAD) of 0.033 mg/kg/day (300X uncertainty factor). For the U.S. population and infants and children, exposures were compared to a lowest-observed-adverse-effect level (LOAEL) of 125 mg/kg/day from an acute neurotoxicity study in rats. Uncertainty factors of 300X and 900X were applied to the LOAEL for the general population and infants and children subgroups, respectively. Acute exposure for the U.S. population was 0.13% of the aPAD of 0.42 mg/kg body weight/day (300X uncertainty factor). For the infants and children populations, the most sensitive population subgroup was non-nursing infants with an exposure of 1.77% of the aPAD of 0.14 mg/kg/day (900X-uncertainty factor). These results show a very large margin of safety associated with the consumption of pymetrozine-treated commodities and even under conservative assumptions all populations receive less than 2% of the acute population adjusted dose.

ii. *Drinking water*. The acute drinking water exposure to pymetrozine was evaluated based on the crops above using EPA's surface water Tier 1 model (GENEEC). Hops with 3 applications at 0.1875 lb ai/acre was the highest contributor at 4.27 ppb. Using the current aPAD of 0.033 mg/kg for females 13+, the margin of exposure percent (MOE%) of risk cup anticipated is 0.43%. For children the aPAD of 0.14 mg/kg yields an MOE% of risk cup of 0.30%.

Hops was also the highest contributor to surface water exposure at 0.31 ppb. Using the current cPAD of 0.0013 mg/kg/day (for females and children) the surface water exposure results in an MOE% of risk cup of 2.38% for children. Using a Q* of 0.0119 the risk to a typical 70 kg adult drinking 2 liters of water per day would be estimated at 1.05×10^{-7}.

2. *Non-dietary exposure*. Pymetrozine is registered on ornamentals and exposure could occur through post-application re-entry to treated plants. Syngenta believes that risks due to short-term, intermediate-term or chronic exposure are either not applicable or insignificant.

D. Cumulative Effects

The potential for cumulative effects of pymetrozine and other substances that have a common mechanism of toxicity has also been considered. Pymetrozine belongs to a new chemical class known as pyridine azomethines and exhibits a unique mode of action. There is no reliable information to indicate that toxic effects produced by pymetrozine would be cumulative with those of any other chemical including another pesticide. Therefore, Syngenta believes it is appropriate to consider only the potential risks of pymetrozine in an aggregate risk assessment.

E. Safety Determination

1. *U.S. population*. Using the exposure assumptions and the proposed RfD described above, the aggregate exposure to pymetrozine will utilize 0.5% of the RfD for the U.S. population. The RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. EPA generally has no concern for exposures below 100 percent of the RfD. In addition, Lifetime cancer risk for the U.S. population was 2.24×10^{-7}, which is below the level of EPA concern. Therefore, Syngenta concludes that there is a reasonable certainty that no harm will result from aggregate exposure to pymetrozine residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of pymetrozine, data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat have been considered.

In a teratology study in rats, developmental toxicity anomalies and variations associated were observed only at maternally toxic doses. Similarly, in a rabbit teratology study, effects were observed only at maternally toxic doses. The NOAELs in the rat and rabbit teratology studies were 30 and 10 mg/kg/day, respectively. In the two-generation rat reproduction study, there were no effects on reproductive parameters. Offspring body weights were slightly reduced and eye opening was slightly delayed at dose levels producing parental toxicity. The NOAEL for parental and offspring toxicity was approximately 1–4 mg/kg/day.

FFDCA section 408 provides that EPA shall apply an additional 10–fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a

different margin of safety will be safe for infants and children. EPA has added an additional 3–fold factor to the acute dietary risk assessment for infants and children due to the lack of a NOAEL in the critical study. An additional 3–fold factor is also needed due to the uncertainty resulting from the data gap for the developmental neurotoxicity study in rats. This latter safety factor is applicable to the following subgroup populations: Females 13–50; infants, children (1–6 years old), and children (7–12 years old) for all risk assessment scenarios for acute and chronic dietary and residential scenarios. No greater additional factor is needed because, using the exposure assumptions described above, the percent of the pymetrozine chronic PAD that will be utilized by the most exposed sub-population (children, 1–6 years old) is 2.5%. Therefore, based on the completeness and reliability of the toxicity database, Syngenta concludes that there is reasonable certainty that no harm will result to infants and children from exposure to pymetrozine residues.

F. International Tolerances

There are no established European (CODEX), Canadian, or Mexican Maximum Residue Limits (MRLs) for pymetrozine. There are provisional MRLs in Germany for hops (10 ppm) and potatoes (0.02 ppm). The European Union is currently evaluating a proposed tolerance of 5 ppm on hops. At this time, international harmonization of residue levels is not an issue.

[FR Doc. 01–18098 Filed 7–18–01; 8:45 a.m.]

BILLING CODE 6560–50–S

FARM CREDIT ADMINISTRATION

Public Meeting on Other Financing Institutions and Alternative Funding Mechanisms

ACTION: Notice of meeting; additional information.

SUMMARY: On July 5, 2001, the Farm Credit Administration (FCA) published a notice announcing a public meeting in Des Moines, Iowa on August 3, 2001 about (1) The funding and discount relationship between other financing institutions (OFIs) and Farm Credit System (FCS or System) banks, and (2) other partnerships between FCS and non-System institutions that would increase the availability of agricultural and rural credit. This notice provides the public with more information about the time, place, and procedures for requesting to speak and submit testimony at the public meeting.

DATES: The public meeting will begin at 8:30 a.m. Central Daylight Time on August 3, 2001 in Des Moines, Iowa.

ADDRESSES: The FCA will hold the public meeting at the Embassy Suites Hotel on the River, 101 East Locust Street, Des Moines, Iowa, 50309 (515) 244–1700. You may submit requests to appear and present testimony for the public meeting by electronic mail to *reg-comm@fca.gov* or through the Pending Regulations section of our Web site at *www.fca.gov.* You may also send your request in writing to Thomas G. McKenzie, Director, Regulation and Policy Division, Office of Policy and Analysis, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090, or by facsimile transmission to (703) 734–5785.

FOR FURTHER INFORMATION CONTACT:

Dennis Carpenter, Senior Policy Analyst, Office of Policy and Analysis, Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090, (703) 883–4498, TDD (703) 883–4444,

or

Richard A. Katz, Senior Attorney, Office of General Counsel, Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090, (703) 883–4020, TDD (703) 883–4444.

SUPPLEMENTARY INFORMATION: On July 5, 2001, we published a notice in the **Federal Register** that the FCA would hold a public meeting about OFIs and other partnerships between System and non-System institutions that increase funding for agriculture and rural America. *See* 66 FR 35429. Our earlier notice told you we would publish the name and address of the meeting facility on our Web site and in the **Federal Register** at least 15 days before the date of the public meeting. This notice informs you of the exact location and time of the public meeting.

I. Request To Present Testimony

As noted in our original Notice of Public Meeting, any interested party wishing to present testimony at the meeting may submit a request to the FCA at one of the addresses we listed at the outset of this notice. You may also identify yourself and your intent to speak the day of the public meeting. In order to provide the most opportunity for interested parties to present their views, we encourage you to testify as part of a panel. A request to speak should provide the name, address and telephone number of the person wishing to testify and the general nature of the testimony. Once we receive your request to testify, we may assign you to a panel and notify you when you are scheduled to speak. As time permits, following any panel presentations, we may accept individual testimony. Also, if time permits, at the end of the public meeting, additional parties who were not scheduled to speak may be invited to provide their thoughts and comments on questions posed in this notice.

II. Written Comments and Testimony

As addressed in our original Notice of Public Meeting, we intend to include all comments in our official public record. For this reason, we ask you to provide us with a written statement or detailed summary of your oral testimony by the close of the public meeting. We also ask, if possible, that you send us an electronic version of your oral testimony before August 3, 2001. If you are not invited to testify because of time constraints, you may give us a written statement, which we will place in the record.

Written copies of the testimony along with a recorded transcript of the proceedings will be included with a recorded transcript of the proceedings will be included in our rulemaking files. We encourage you to bring extra copies of your written statement (we suggest 50 copies) for distribution to the press and other interested parties attending the public meeting.

The FCA Board will accept written comments, in support of or in rebuttal to testimony presented at the public meeting or comments submitted for the record. The comment period for such additional comments will end 30 days following the date of this public meeting. The comments, as well as all documents and testimony received by the FCA as part of the public meeting process, will be available for public inspection at the FCA's offices Office of Policy and Analysis in McLean, Virginia.

Dated: July 16, 2001.

Kelly Mikel Williams,

Secretary, Farm Credit Administration Board.

[FR Doc. 01–18056 Filed 7–18–01; 8:45 am]

BILLING CODE 6705–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission

July 10, 2001.

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 of 1995, Public Law 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 (PRA) 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 comments should be submitted on or before August 20, 2001. 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 comments to Judy Boley, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., DC 20554 or via the Internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judy Boley at 202–418–0214 or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0655.

Title: Requests for Waivers of Regulatory and Application Fees Predicated on Allegations of Financial Hardship.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households, businesses or other for-profit.

Number of Respondents: 240.

Estimated Time Per Response: 1 hour.

Frequency of Response: On occasion reporting requirement and recordkeeping requirement.

Total Annual Burden: 240 hours.

Total Annual Cost: $3,200.

Needs and Uses: Pursuant to 47 U.S.C. 159, the FCC is required to collect annual regulatory fees from its licensees and permittees. Licensees and permittees may request waivers of the annual regulatory and application fees on grounds of financial hardship. The subject orders lists the types of documents or financial reports which are ordinarily maintained as business records or can be easily assembled, which may be submitted to support claims of financial hardship. The information is used by the FCC to determine if a party is entitled to the waiver.

OMB Control No.: 3060–0502.

Title: Section 73.1942, Candidate Rates.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Businesses or other for-profit.

Number of Respondents: 11,878 respondents; 296,950 responses.

Estimated Time Per Response: .5–20 hours.

Frequency of Response: Recordkeeping requirement, third party disclosure requirement, and on occasion reporting requirement.

Total Annual Burden: 671,107 hours.

Total Annual Cost: N/A.

Needs and Uses: Section 73.1942 requires broadcast licensees to disclose station practices offered to commercial advertisers that enhance the value of advertising spots and different classes of time. It also requires licensees to calculate the lowest unit charge and periodically review advertising records. The disclosure would allow candidates to determine that they are receiving the same charge as the most favored advertiser. The review of advertising records determines whether compliance with this section requires that candidates receive rebates or credits.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–17987 Filed 7–18–01; 8:45 am]

BILLING CODE 6712–01–U

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collections Approved by Office of Management and Budget

July 12, 2001.

The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collections pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13. 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 control number. For further information contact Shoko B. Hair, Federal Communications Commission, (202) 418–1379.

Federal Communications Commission

A. OMB Control No.: 3060–0853.

Expiration Date: December 31, 2001.

Title: Receipt of Service Confirmation Form, and Adjustment of Funding Commitment, and Certification by Administrative Authority to Billed Entity of Compliance with Children's Internet Protection.

Form No.: FCC Form 486, FCC Form 500, and FCC Form 479.

Respondents: Not for profit institutions; business or other for-profit.

Estimated Annual Burden: 40,000 respondents; 15.37 hours per response (avg.); 615,000 total annual burden hours (for all collections approved under this control number).

Estimated Annual Reporting and Recordkeeping Cost Burden: $0.

Frequency of Response: On occasion; third party disclosure.

Description: In a Report and Order issued in CC Docket No. 96–45, (FCC 01–120), released April 5, 2001, the Commission adopted rules to implement the Children's Internet Protection Act (CIPA). Congress included CIPA as part of the Consolidated Appropriations Act, 2001. Sections 1721 *et seq.* of CIPA provide that schools and libraries that have computers with Internet access must certify that they have in place certain Internet safety policies and technology protection measures in order to be eligible under section 254(h) of the Communications Act of 1934, as amended (the Act), to receive discounted Internet access, Internet services, and internal connection services. CIPA also requires that our rules implementing the statute be in effect by April 20, 2001. Specifically, in order to receive discounts for Internet access and internal connections services under the universal service support mechanism, school and library authorities must certify that they are enforcing a policy of Internet safety that includes measures to block or filter Internet access for both minors and adults to certain visual depictions. A school administrative authority must certify that its policy of Internet safety includes monitoring the online activities of minors. In order to receive discounts, school and library authorities must also certify that they had adopted and implemented an Internet safety

policy addressing (i) access by minors to inappropriate matter on the Internet and World Wide Web; (ii) the safety and security of minors when using electronic mail, chat rooms, and other forms of direct electronic communications; (iii) unauthorized access; (iv) unauthorized disclosure, use, and dissemination of personal information regarding minors; and (v) measures designed to restrict minors' access to materials harmful to minors. For this funding year, schools and libraries must certify by October 28, 2001 that they have the policies and technology measures in place, or that they are undertaking such actions, including any necessary procurement procedures, to put them in place for the following funding year. Schools and libraries shall make the necessary certification in FCC Form 486, Receipt of Service Confirmation Form, which has been modified to incorporate procedures pursuant to CIPA. In cases involving consortia (or certain similar entities), the consortium leader will certify that it has received the certification required by CIPA from individual consortium members. All members the consortium must submit signed certifications to the billed entity of each consortium on a new form, FCC Form 479, Certification by Administrative Authority to Billed Entity of Compliance with Children's Internet Protection Act. The Billed Entity will be required to retain copies of the signed and completed FCC Form 479. See 47 CFR Section 54.520. The Commission did not modify FCC Form 500. The forms and instructions may be obtained at the SLD website, *http://www.sl.universalservice.org/*, or by contacting the SLD Client Service Bureau at 888–203–8100. Obligation to respond: Mandatory.

B. OMB Control No.: 3060–0774.

Expiration Date: June 30, 2004.

Title: Federal-State Joint Board on Universal Service, CC Docket No. 96–45 (47 CFR Sections 36.611 and 36.612 and 47 CFR Part 54).

Form No.: N/A.

Respondents: Not for profit institutions; business or other for-profit; State, Local or Tribal Government.

Estimated Annual Burden: 5,554,651 respondents; .33 hours per response (avg.); 1,853,807 total annual burden hours (for all collections approved under this control number).

Estimated Annual Reporting and Recordkeeping Cost Burden: $0.

Frequency of Response: On occasion; Quarterly; Annually; Third Party Disclosure; Recordkeeping.

Description: Congress directed the Commission to implement a new set of universal service support mechanisms that are explicit and sufficient to advance the universal service principles enumerated in 47 U.S.C. 254 and other such principles as the Commission believes are necessary and appropriate for the protection of the public interest, convenience and necessity, and are consistent with the Communications Act of 1934, as amended. Part 54 promulgates the rules and requirements to preserve and advance universal service. The collections are necessary to implement Section 254.

a. 47 CFR 36.611(a) & 36.612—Submission and updating information to the National Exchange Carrier Association. (No. of respondents: 1340; hours per response: 20 hours; total annual response: 26,900 hours).

b. 47 CFR 54.101(c)—Demonstration of exceptional circumstances. (No. of respondents: 50; hours per response: 2 hours; total annual burden: 100 hours).

c. 47 CFR 54.201(a)(2)—Submission of eligibility criteria. (No. of respondents: 100; hours per response: 4 hours; total annual burden: 400 hours).

d. 47 CFR 54.201(b)–(c)—Submission of eligibility criteria. (No. of respondents: 3400; ours per response: 1 hour; total annual burden: 3400 hours).

e. 47 CFR 54.201(d)(2)—Advertisement of services and charges. (No. of respondents: 1300; hours per response: 50 hours; total annual hours: 65,000).

f. 47 CFR 54.205(a)—Advance notice of relinquishment of universal service. (No. of respondents: 100; hours per response: .5 hours; total annual burden: 50 hours).

g. 47 CFR 54.207(c)(1)—Submission of proposal for redefining a rural service area. (No. of respondents: 50; hours per response: 5 hours per study area or 125 hours per state; total annual burden: 6250 hours).

h. 47 CFR 54.301—Local Switching support. See OMB control number 3060–0814.

i. 47 CFR 54.307—Reporting of expenses and number of lines served. (No. of respondents: 1300; hours per response: 2 hours to report lines and 4 hours to prepare cost study; total annual burden: 5400 hours).

j. 47 CFR 54.309—Petition for waiver. (No. of respondents: 51; hours per response: 4 hours; total annual burden: 204 hours).

k. 47 CFR 54.311—Petition for waiver. (No. of respondents: 51; hours per response: 4 hours; total annual burden: 204 hours).

l. 47 CFR 54.401(b)(1)–(2)—Submission of disconnection waiver request. (No. of respondents: 50; hours per response: 2 hours; total annual burden; 100 hours).

m. 47 CFR 54.401(d)—Lifeline certification and plans. (No. of respondents: 1300; hours per response: 1 hour; total annual burden: 1300 hours).

n. 47 CFR 54.403—Certifications Required by 47 CFR 54.403. (No. of respondents: 170,187; hours per response: .33 hours; total annual burden: 56,729 hours).

o. 47 CFR 54.405 and 54.411—Carrier Publicizing of Lifeline and Link Up Services. (No. of respondents: 2414; hours per response: 50 hours; total annual burden; 120,700 hours).

p. 47 CFR 54.407(c)—Lifeline record keeping. (No. of respondents: 1300; hours per response: 80 hours; total annual burden: 104,000 hours).

q. 47 CFR 54.409 and § 54.415—Consumer qualification for Lifeline. (No. of respondents: 5.5 million; hours per response: .08 hours; total annual burden: 440,000 hours).

r. 47 CFR 54.409(c)—Consumer notification of Lifeline discontinuance. (No. of respondents: 550,000; hours per response: .08 hours; total annual burden: 44,000 hours).

s. 47 CFR 54.413(b)—Link Up record keeping. (No. of respondents: 1300; hours per response: 80 hours; total annual burden: 104,000 hours).

t. 47 CFR 54.501(d)(3) & 54.516—Schools and libraries record keeping. (No. of respondents: 53,400; hours per response: 80 hours; total annual burden: 372,000 hours).

u. 47 CFR 54.504(b)–(d), 54.505(b)(1), (2), 54.507(d) & 54.509(a)—Description of services requested and certification. See also OMB control number 3060–0806.

v. 47 CFR 54.519—State telecommunications networks. (No. of respondents: 50; hours per response: 4 hours; total annual burden: 200 hours).

w. 47 CFR 54.601(b)(4) & 54.609—(No. of respondents: 3400; hours per response: 100 hours; total annual burden: 340,000 hours).

x. 47 CFR 54.601(b)(3) & 54.619—Shared facility record keeping. (No. of respondents: 15,400; hours per response: 40 hours for 3400 telecommunications carriers and 2 hours for 12,000 health care providers; total annual burden: 160,000 hours).

y. 47 CFR 54.607(b)(1)–(2)—Submission of proposed rural rate. (No. of respondents: 50; hours per response: 3 hours; total annual burden: 150 hours).

z. 47 CFR 54.603(b)(1), 54.615(c)–(d), & 54.623(d)—Description of services requested and certification. See also OMB control number 3060–0804.

aa. 47 CFR 54.619(d)—Submission of rural health care report (No. of respondent: 1; hours per response: 40 hours; total annual burden: 40 hours).

bb. 47 CFR 54.701(f)(1) & (f)(2)—Submission of annual report & CAM. (No. of respondents: 1; hours per response: 40 hours; total annual burden: 40 hours).

cc. 47 CFR 54.701(g)—Submission of quarterly report. (No. of respondents: 1; hours per response: 10 hours; total annual burden: 40 hours).

dd. 47 CFR 54.707—Submission of state commission designation. (No. of respondents: 3400; hours per response: .25 hours; total annual burden: 850 hours).

ee. Obligation to notify underlying carrier. (No. of respondents: 1700; hours per response: 1 hour; total annual burden: 1700 hours).

ff. Demonstration of Reasonable Steps. (No. of respondents: 50; hours per response: 1 hour; total annual burden: 50 hours).

All the requirements contained herein are necessary to implement the congressional mandate for universal service. These reporting requirements are necessary to calculate the contribution amount owed by each telecommunications carrier or to verify that particular carriers and other respondents are eligible to receive universal service support. The recordkeeping requirements should not be burdensome since most businesses ordinarily retain these types of documents. Obligation to respond: Mandatory.

Public reporting burden for the collections of information are as noted above. Send comments regarding the burden estimates or any other aspect of the collections of information, including suggestions for reducing the burden to Performance Evaluation and Records Management, Washington, DC 20554.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–18055 Filed 7–18–01; 8:45 am]

BILLING CODE 6712–01–U

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 94–102; DA 01–1628]

Petition for Waiver of E911 Phase II Rules; Comments Invited

AGENCY: Federal Communications Commission.

ACTION: Solicitation of comments.

SUMMARY: The document invites comment on a Petition for Waiver (Petition) of the Commission's E911 Phase II rule filed July 6, 2001, by Cingular Wireless LLC (Cingular). Current Phase II rules require wireless carriers to begin to deploy the capability to identify the precise location of wireless 911 calls beginning on October 1, 2001, provided that certain conditions are met. This capability is called Phase II Automatic Location Identification (ALI). The Phase II rules establish deployment schedules and set accuracy and reliability requirements for both handset-based and network-based ALI technologies.

Cingular requested a waiver of Phase II rules to permit it to deploy a hybrid network and handset-base technology called Enhanced Observed Time Difference of Arrival (E–OTD) throughout its Global System for Mobil Communications (GSM) air interface network and a switch-based technology, similar to Mobile-Assisted Network Location System for its Time Division Multiple Access network.

The full text of the petition is available for public inspection during regular business hours in the FCC Public Reference Room, Room CY–A257, 445 12th Street, SW., Washington, DC 20554. Pursuant to 47 CFR 1.1200(a), this proceeding is designated as a ''permit but disclose'' proceeding and subject to § 1.1206 of the Commission's Rules. Presentations to or from Commission decision making personnel are permissible, provided that *ex parte* presentations are disclosed pursuant 47 CFR 1.1206(b).

Interested parties may file comments responding to the Petition on or before July 31, 2001, and reply comments on or before August 10, 2001. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. Comments filed through ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.hmtl.* Only one copy of an electronic submission must be filed. In completing the transmittal screen, commenters should include their full name, postal service mailing address, and the applicable docket or rulemaking number of this proceeding.

Parties may also submit an electronic comment by Interest e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to *ecfs@fcc.gov,* and should include the following words in the body of the message, ''get form<your e-mail address>.'' A sample form and directions will be sent in reply. Parties who choose to file by paper must file an original and four copies of each filing.

DATES: Comments are due on or before July 31, 2001, and reply comments are due on or before August,10, 2001.

ADDRESSES: All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554. A copy should also be sent to Jennifer Salhus, Room 3A–131, Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jennifer Salhus, 202–418–1310.

Federal Communications Commission

Thomas J. Sugrue,

Chief, Wireless Telecommunications Bureau.

[FR Doc. 01–18128 Filed 7–18–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 94–102; DA 01–1650]

Petition for Waiver of E911 Phase II Rules; Comments Invited

AGENCY: Federal Communications Commission.

ACTION: Solicitation of comments.

SUMMARY: The document invites comment on a Petition for Waiver (Petition) of the Commission's E911 Phase II rules, filed June 22, 2001, by Corr Wireless Communications, LLC (Corr). Current Phase II rules require wireless carriers to provide the precise location of wireless 911 calls to Public Safety Answering Points (PSAPs), a technological capability known as Automatic Location Identification (ALI). The rules permit wireless carriers to ''phase-in'' either a network-based or handset-based ALI technology. Handset-based solutions may be gradually phased in beginning October 1, 2001. Carriers employing network solutions are required to provide Phase II service to 50 percent of the PSAP's coverage area or population on October 1, 2001, or within six months of a PSAP request, whichever is later, and 100 percent of the PSAP's coverage area or population within a year thereafter.

Corr requested a temporary waiver of the Commission's Phase II rules to permit the carrier to deploy its network solution in conformity with its proposed graduated implementation schedule. Corr indicates that the Commission's six-month implementation deadline applicable to network-based solutions has been triggered by recent PSAP requests in its service area. According to Corr, the network solution is prohibitively expensive and a graduated

implementation schedule is warranted to ease the economic burden on the carrier. Under Corr's proposed schedule, it will immediately order and install the switch-related infrastructure necessary to provide Phase II service. Thereafter, Corr proposes to provide service to the top 35 percent (measured by 911 service) of the cell sites of any requesting jurisdiction within 9 months of receiving a request, and 50 percent and 75 percent of cell sites within 12 months and 18 months, respectively.

The full text of the petition is available for public inspection during regular business hours in the FCC Public Reference Room, Room CY–A257, 445 12th Street, SW., Washington, DC 20554. Pursuant to 47 CFR 1.1200(a), this proceeding is designated as a ''permit but disclose'' proceeding and subject to § 1.1206 of the Commission's Rules. Presentations to or from Commission decision making personnel are permissible, provided that *ex parte* presentations are disclosed pursuant 47 CFR 1.1206(b).

Interested parties may file comments responding to the Petition on or before July 26, 2001, and reply comments on or before August 6, 2001. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. Comments filed through ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.hmtl.* Only one copy of an electronic submission must be filed. In completing the transmittal screen, commenters should include their full name, postal service mailing address, and the applicable docket or rulemaking number of this proceeding. Parties may also submit an electronic comment by Interest e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to *ecfs@fcc.gov,* and should include the following words in the body of the message, ''get form<your e-mail address>.'' A sample form and directions will be sent in reply. Parties who choose to file by paper must file an original and four copies of each filing.

DATES: Comments are due on or before July 26, 2001, and reply comments are due on or before August 6, 2001.

ADDRESSES: All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554. A copy should also be sent to Steven Rangel, Room 8A–831, Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Daniel Grosh and Steven Rangel, 202–418–1310.

Federal Communications Commission

Thomas J. Sugrue,

Chief, Wireless Telecommunications Bureau.

[FR Doc. 01–18129 Filed 7–18–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

DATE & TIME: *Tuesday, July 24, 2001 at 10 a.m.*

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

PREVIOUSLY ANNOUNCED DATE & TIME: Thursday, July 26, 2001. *Meeting open to the public.*

This meeting has been cancelled.

PERSON TO CONTACT FOR INFORMATION: Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 01–18250 Filed 7–17–01; 3:29 pm]

BILLING CODE 6715–01–M

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuances

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, as amended by the Ocean Shipping Reform Act of 1998 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR 515.

License No.	Name/address	Date reissued
692F	A.R. Savage & Son, Inc., 1803 Eastport Drive, Tampa, FL 33605	May 4, 2001.
4088F	Able Freight Services, Inc., 801 W. Hyde Park Blvd., Inglewood, CA 90302	May 10, 2001.
10873N	Ameripack Services, Inc., 7301 NW 41st Street, Miami, FL 33166	April 22, 2001.
4268F	J & S Universal Services, Inc., dba Patrick & Rosenfeld Shipping Corp., 4453 NW 97th Avenue, Miami, FL 33178.	March 22, 2001.
3964F	Logistic Excel Corporation, 1521 West Magnolia, Suite B, Burbank, CA 91506	April 27, 2001.
2468F	USA Cargo Services Co., 1343 Terrell Mill Road, Suite 200, Marietta, GA 30067–9472.	June 22, 2001.

Sandra L. Kusumoto,

Director, Bureau of Consumer Complaints and Licensing.

[FR Doc. 01–17992 Filed 7–18–01; 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. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, effective on the corresponding dates shown below:

LICENSE NUMBER: 777NF

NAME: A.W. Fenton Company, Inc.

ADDRESS: 21500 Aerospace Parkway, Brook Park, OH 44142–1071.

DATE REVOKED: June 4, 2001.

REASON: Surrendered license voluntarily.

LICENSE NUMBER: 11082NF.

NAME: NASCO Maritime Inc.

ADDRESS: 9432 Bellanca Avenue, Los Angeles, CA 90045.

DATE REVOKED: June 7, 2001.

REASON: Failed to maintain valid bonds.

LICENSE NUMBER: 2247F.

NAME: Sina International Forwarders, Inc.

ADDRESS: 9432 Bellanca Avenue, Los Angeles, CA 90045.

DATE REVOKED: June 7, 2001.

REASON: Failed to maintain a valid bond.

Sandra L. Kusumoto,

Director, Bureau of Consumer Complaints and Licensing.

[FR Doc. 01–17991 Filed 7–18–01; 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

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 2, 2001.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) 600 Atlantic Avenue, Boston, Massachusetts 02106-2204:

1. John D. Doherty and Joseph R. Doherty, Somerville, Massachusetts; to acquire more than 10 percent of the voting shares of Central Bancorp, Inc., Somerville, Massachusetts.

B. Federal Reserve Bank of Cleveland (Paul Kaboth, Banking Supervision) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. Janet M. Williams, individually, as trustee of the B. Anthony Williams Trust, and as executor of the estate of B. Anthony Williams, and Janet M. Williams, Lynn Williams Cowan, Beth Leah Ellingerwood, Brooke Allison Williams, Dana Love Williams, Margaret Constance Ellingwood, James Whittaker Ellingwood, and the B. Anthony Williams Trust; all members of the Williams Family acting in concert, all of Wilmington, Ohio; to retain voting shares of NB&T Financial Group, Inc., Wilmington, Ohio, and thereby indirectly retain shares of National Bank & Trust Company, Wilmington, Ohio.

Board of Governors of the Federal Reserve System, July 13, 2001.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 01–17989 Filed 7–18–00; 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 August 10, 2001.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. MB-MidCity, Inc., Chicago, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of MB Financial, Inc., Chicago, Illinois; Manufacturers National Corporation, Chicago, Illinois; Manufacturers Bank, Chicago, Illinois; MidCity Financial Corporation, Chicago, Illinois; Abrams Centre Bancshares, Inc., Dallas, Texas; Abrams Centre National Bank, Dallas, Texas; Union Bank and Trust Company, Oklahoma City, Oklahoma; First National Bank of Elmhurst, Elmhurst, Illinois, First National Bank of Morton Grove, Morton Grove, Illinois; and The Mid-City National Bank of Chicago, Chicago, Illinois.

In connection with this application, Applicant also has applied to acquire Summit MFR Leasing LLC, Cincinnati, Ohio, and Sentry Lease Equity Pool 2000-1, LLC, Salt Lake City, Utah, and thereby engage in leasing personal or real property, pursuant to § 225.28(b)(3) of Regulation Y.

B. Federal Reserve Bank of San Francisco (Maria Villanueva, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105–1579:

1. BNP Paribas, Paris, France; to acquire 100 percent of the voting shares of BancWest Corporation, Honolulu, Hawaii, and thereby indirectly acquire Bank of the West, San Francisco, California, and First Hawaiian Bank, Honolulu, Hawaii.

Board of Governors of the Federal Reserve System, July 13, 2001.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 01–17990 Filed 7–18–00; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Rules of Organization

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Revision of rules of organization.

SUMMARY: The Secretary of the Board has approved technical corrections to the Board's Rules of Organization to reflect organizational changes. The revisions will bring descriptions of the functions of central and field organizations up to date.

DATES: The revised Rules of Organization are effective August 20, 2001.

FOR FURTHER INFORMATION CONTACT: Robert deV. Frierson, Associate Secretary of the Board (202/452–3711), Office of the Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: The Board's Rules of Organization is an uncodified regulation issued as required by section 552(a)(1) of the Freedom of Information Act, 5 U.S.C. 552(a)(1), and is revised to read as follows:

Section 1—Basis and Scope

These rules are issued by the Board of Governors of the Federal Reserve System (''the Board'') pursuant to the requirement of section 552 of title 5 of the United States Code that each agency shall publish in the **Federal Register** a description of its central and field organization.

Section 2—Composition, Location, and Public Information

(a) *Members, Chairman, Vice Chairman.* The Board consists of seven members appointed by the President, by and with the advice and consent of the Senate, for 14-year terms. The members of the Board are required by law to devote their entire time to the business of the Board. One member is designated by the President as Chairman and one as Vice Chairman, to serve in those positions for terms of four years. At meetings, the Chairman presides or, in the Chairman's absence, the Vice Chairman presides. In the absence of the Chairman and Vice Chairman, the member of the Board present with the longest service acts as Chairman. The Chairman of the Board, subject to its supervision, is its active executive officer. The Board meets regularly to consider matters related to monetary and credit policies, its regulatory and supervisory duties under various statutes, and administrative and other questions related to its responsibilities.

(b) *Location and business hours.* The principal offices of the Board are at 20th Street and Constitution Avenue, NW., Washington, DC 20551. The public entrance is at 20th and C Streets, NW. The Board's regular business hours are from 8:45 a.m. to 5:15 p.m. each weekday, but its business hours may be changed from time to time.

(c) *Public information.* Public information about the Board and its actions may be obtained from the Freedom of Information Office at the principal offices of the Board during regular business hours or from the Board's Internet site at www.federalreserve.gov. Requests for information or submissions to the Board may be sent to the Secretary of the Board at its principal offices.

Section 3—Central Organization

The Board's central organization consists of the members of the Board and the following offices, divisions, and officials:

(a) *Office of Board Members* consists of the members of the Board, and assistants and special assistants to the Board assigned to public affairs and congressional liaison.

(b) *Division of Monetary Affairs,* headed by a director, is responsible for planning and coordinating programs, memoranda, and analyses and presenting decision-making options in areas of monetary and closely related financial policies. Responsibilities are carried out through various staff activities, including preparation of position papers and other documents on monetary policy issues such as open market, discount, and reserve requirement policy; coordination of analysis of regulatory and statistical issues closely related to monetary policy, including publication and interpretation of a variety of statistical series on money, reserves, and interest rates; and liaison with the trading desk at the Federal Reserve Bank of New York in connection with open market operations and market developments.

(c) *Office of Staff Director for Management,* who reports to members of the Board, is responsible for the planning and coordination of Board operations and the management of Board resources. The Staff Director exercises authority over Board divisions in the areas of strategic planning, budgeting and financial management, human resources management, information technology, facilities management, and continuity of operations and exercises line authority over the divisions of Management, Information Technology, and Support Services. The Staff Director also oversees the Board's work with the Office of Management and Budget, the General Accounting Office, the Congressional Budget Office, and other federal agencies.

(d) *Management Division,* currently headed by the Staff Director for Management, is responsible for supporting strategic planning and providing support to the Board in the areas of finance, human resources, and equal employment opportunity. The division is also responsible for maintaining the Board's management policies and procedures.

(e) *Office of the Secretary,* headed by the Secretary of the Board, coordinates and handles items requiring Board action, including actions under delegated authority; prepares agendas for Board meetings; implements actions taken at Board meetings; prepares, circulates, and indexes minutes of the Board; publishes the *Federal Reserve Regulatory Service* and related manuals; oversees the selection of Federal Reserve Bank and Branch directors; provides liaison at the staff level with the Federal Advisory Council, the Thrift Institutions Advisory Council, and other groups; makes arrangements for Board and System conferences at the Board; maintains custody of, and provides reference service in connection with, official records of the Board; handles correspondence and requests from the public for records; secures passports and visas for official travel of System personnel; and provides relief secretarial services.

(f) *Legal Division,* headed by the General Counsel, advises the Board in carrying out its statutory and regulatory responsibilities by preparing Board decisions, regulations, rules, instructions, and legal interpretations of statutes and regulations administered by the Board; represents the Board in civil litigation and administrative proceedings; assists other divisions in fulfilling their responsibilities in such areas as contracting, fiscal agency activities, Federal Reserve Bank matters, labor law, personnel, and supervisory enforcement matters; and prepares testimony or comments on proposed legislation.

(g) *Division of Research and Statistics,* headed by a director, provides the Board and the Federal Open Market Committee with the economic analysis and information needed for current operations, for the formulation of monetary and credit policies, and for the exercise of responsibilities regarding bank regulation; prepares, publishes, and interprets a variety of statistical series in the financial and nonfinancial fields; and conducts basic research related to the effects of monetary policy on economic activity and prices and to the effects of financial regulation on the structure and functioning of financial markets.

(h) *Division of International Finance,* headed by a director, provides the Board, the Federal Open Market Committee, and other System officials with assessments of current international economic and financial developments. Staff members analyze major economic and financial developments abroad, issues connected with exchange-market developments, international financial flows and their implications, the international monetary and financial systems and their evolution, and the balance-of-payments adjustment process. The division provides economic data and analyses for public release. It also works with the Chairman and other Board members in their roles as members of various

interagency bodies dealing with international economic policy issues.

(i) *Division of Reserve Bank Operations and Payment Systems,* headed by a director, advises and assists the Board in its oversight of Reserve Banks as providers of financial services to depository institutions, the Department of the Treasury, and other government agencies. This oversight includes assessment of the future direction of the Reserve Banks' operations and services, the implementation of major initiatives, and ongoing operations. The division evaluates the efficiency and effectiveness of, and the adequacy of controls over, Reserve Bank financial and fiscal agency services, and most Reserve Bank support functions, such as information technology, human resources, financial and cost accounting, operating and capital budgeting, facilities management, and internal audit. The division prescribes accounting principles, standards, and related requirements to be followed by the Reserve Banks. In addition, it coordinates the printing and distribution of Federal Reserve notes.

The division recommends to the Board policies and regulations to foster the integrity and efficiency of the U.S. payment system; works closely with other central banks, the private sector, international organizations, and other interested parties to improve the payment system more broadly; and conducts research on various payments issues. It also coordinates with the Department of the Treasury and other government agencies to facilitate the System's role as fiscal agent to the United States.

(j) *Division of Banking Supervision and Regulation,* headed by a director, coordinates the System's supervision of banks and bank holding companies and oversees and evaluates the Reserve Banks' examination procedures; exercises general supervision of the banking, fiduciary, and information technology activities of state member banks, bank holding companies and their nonbank subsidiaries, and other financial entities supervised by the Board; administers laws, regulations, and supervisory policies relating to state member banks, bank holding companies, financial holding companies, nonbank subsidiaries, Edge and agreement corporations, foreign banks with domestic operations, and persons related to those institutions; supervises various foreign banking activities of member banks and foreign banking organizations; processes and presents to the Board applications filed under the Bank Holding Company Act of 1956, the Bank Merger Act, the Federal Reserve Act, and various other related statutes; coordinates supervisory activities with other regulators, such as the Securities and Exchange Commission and state insurance authorities, as required by the Gramm-Leach-Bliley Act; and advises the Board about developments in banking and in bank supervisory policies and procedures.

(k) *Division of Consumer and Community Affairs,* headed by a director, administers consumer affairs legislation for which the Board has responsibility. Its functions include drafting regulations that implement the Truth in Lending Act, the Equal Credit Opportunity Act, the Community Reinvestment Act, the Home Mortgage Disclosure Act, the Fair Credit Billing Act, the Home Ownership and Equity Protection Act, the Consumer Leasing Act, the Electronic Fund Transfer Act, the Fair Credit Reporting Act, and the Federal Trade Commission Improvements Act. It oversees policy development and monitors the System's examination and enforcement activities regarding compliance by state member banks with these laws and with the Fair Debt Collection Practices Act, the Fair Housing Act, the Flood Disaster Protection Act, and the Real Estate Settlement Procedures Act, as well as Regulation Q (Interest on Deposits). The division also administers the System's consumer complaint program; reviews bank and bank holding company applications with respect to community reinvestment and consumer compliance matters; oversees the community affairs programs of the Reserve Banks, which provide information, education, and technical assistance regarding community development lending and other matters; conducts consumer research; and develops educational initiatives as an alternative or an adjunct to regulation.

(l) *Division of Support Services,* headed by a director, manages the operation of all support programs necessary for the Board to conduct its daily business. These programs include building and office services, facilities management, and logistical and administrative operations. The division is also responsible for the management and operation of the personnel security program for the System; environmental safety plans and programs under applicable environmental protection laws and the Occupational Safety and Health Act; and the development and implementation of strategic plans for major capital replacements, acquisitions, and renovations.

(m) *Division of Information Technology,* headed by a director, is responsible for the overall planning, acquisition, implementation, operation, and maintenance of the Board's automation and telecommunications equipment, operating and data base systems software, and other hardware and software required at the Board; information security; mainframe linkage to distributed processing; and the Board's Internet site. The division is also responsible for the design, development, and implementation of applications software; for the collection, processing, and maintenance of statistical and regulatory data provided by commercial banks, bank holding companies, other financial institutions, and Federal Reserve Banks; and for the provision of technical consulting services related to automation activities in other Board divisions and offices.

(n) *Office of Inspector General* is required by the Inspector General Act of 1978, as amended, to conduct and supervise independent and objective audits, investigations, and other reviews of Board programs and operations; promote economy, efficiency, and effectiveness within the Board; prevent and detect fraud, waste, and mismanagement in the Board's programs and operations; review and make recommendations regarding possible improvements to existing and proposed legislation and regulations related to Board programs and operations; and keep the Chairman and Congress fully and currently informed of problems.

In addition, the Federal Deposit Insurance Act, as amended, requires the Office of Inspector General to review the failure of any financial institution supervised by the Board that results in a material loss to deposit insurance funds and to produce, within six months of the loss, a report that includes possible suggestions for improvement in the Board's banking supervision practices. Through an agreement with the Inspectors General for the other federal financial institutions regulatory agencies, the Board's Office of Inspector General will also investigate any material loss to deposit insurance funds caused by the failure of any financial institution supervised by one of these agencies if that institution is a subsidiary of a Board-regulated holding company.

(o) *Other personnel.* The Board does not employ administrative law judges or hearing officers as regular members of its staff. However, in accordance with applicable law and in individual cases, the Board obtains and uses administrative law judges and hearing

officers, whose functions are separated from investigative and prosecuting functions of the staff.

Section 4—Field Organization

(a) *Federal Reserve Banks.* The United States is divided into 12 Federal Reserve Districts. A Federal Reserve Bank is located in one city in each Federal Reserve District. Ten of the Federal Reserve Banks have one or more Branches in other cities, and in some Districts there are offices or facilities with specialized functions. Each Federal Reserve Bank is a separate legal entity, created pursuant to the Federal Reserve Act and operating under the general supervision of the Board. The locations of the 12 Federal Reserve Banks and the 25 Federal Reserve Branches are shown in the appendix. Each Federal Reserve Bank, in addition to its other duties, carries out local functions for the Board pursuant to instructions of the Board, and in many matters acts as the Board's field representative in the Bank's District. Each Reserve Bank assists in the regional administration of the Board's regulations and policies, keeps the Board informed of local conditions, and recommends actions it thinks appropriate in particular cases. In general, persons concerned with Federal Reserve matters should deal in the first instance with the Federal Reserve Bank of the appropriate District or a Branch thereof, and the Board requests all persons to follow this procedure.

(b) *Federal Reserve agents.* Each Federal Reserve Bank has nine directors, three of whom are appointed by the Board. One of the directors appointed by the Board is designated by the Board as chairman of the board of directors of the Bank and as Federal Reserve agent. This director acts as the Board's official representative and maintains a local office of the Board on the premises of the Federal Reserve Bank.

Section 5—Delegations of Authority

The Board does not delegate any of its functions relating to rulemaking or pertaining principally to monetary or credit policies or involving any questions of general policy. However, the Board delegates certain of its supervisory and other functions prescribed by statute or Board regulation to its members or employees or to the Federal Reserve Banks as provided in its Rules Regarding Delegation of Authority (12 CFR 265) and in specific Board actions. In addition, the Board delegates to the Federal Reserve Banks certain functions not provided for by statute or Board regulation, including authority to extend the time within which certain transactions may be consummated.

Appendix—Federal Reserve Banks

*Boston**

600 Atlantic Avenue, Boston, Massachusetts 02106

*New York**

33 Liberty Street (Federal Reserve P.O. Station), New York, New York 10045

Buffalo Branch
160 Delaware Avenue, Buffalo, New York 14202 (P.O. Box 961, Buffalo 14240–0961)

Philadelphia

Ten Independence Mall, Philadelphia, Pennsylvania 19106 (P.O. Box 66, Philadelphia 19105)

*Cleveland**

1455 East Sixth Street, Cleveland, Ohio 44114 (P.O. Box 6387, Cleveland 44101)

Cincinnati Branch
150 East Fourth Street, Cincinnati, Ohio 45202 (P.O. Box 999, Cincinnati 45201–0999)

Pittsburgh Branch
717 Grant Street, Pittsburgh, Pennsylvania 15219 (P.O. Box 867, Pittsburgh 15230)

*Richmond**

701 East Byrd Street, Richmond, Virginia 23219 (P.O. Box 27622, Richmond 23261)

Baltimore Branch
502 S. Sharp Street, Baltimore, Maryland 21201 (P.O. Box 1378, Baltimore 21203)

Charlotte Branch
530 East Trade Street, Charlotte, North Carolina 28202 (P.O. Box 30248, Charlotte 28230)

Atlanta

1000 Peachtree Street N.E., Atlanta, Georgia 30309–4470

Birmingham Branch
524 Liberty Parkway, Birmingham, Alabama 35242

Jacksonville Branch
800 Water Street, Jacksonville, Florida 32204 (P.O. Box 929, Jacksonville 32231–0044)

Miami Branch
9100 Northwest 36th Street, Miami, Florida 33178 (P.O. Box 520847, Miami 33152–0847)

Nashville Branch
301 Eighth Avenue, North, Nashville, Tennessee 37203 (P.O. Box 4407, Nashville 37203–4407)

New Orleans Branch
525 St. Charles Avenue, New Orleans, Louisiana 70130 (P.O. Box 61630, New Orleans 70161–1630)

*Chicago**

230 South LaSalle Street, Chicago, Illinois 60604 (P.O. Box 834, Chicago 60690–0834)

Detroit Branch
160 W. Fort Street, Detroit, Michigan 48226 (P.O. Box 1059, Detroit 48231)

St. Louis

411 Locust Street, St. Louis, Missouri 63102 (P.O. Box 442, St. Louis 63166)

Little Rock Branch
325 West Capitol Avenue, Little Rock, Arkansas 72201 (P.O. Box 1261, Little Rock 72203–1261)

Louisville Branch
410 South Fifth Street, Louisville, Kentucky 40202 (P.O. Box 32710, Louisville 40232–2710)

Memphis Branch
200 North Main Street, Memphis, Tennessee 38103 (P.O. Box 407, Memphis 38101–0407)

Minneapolis

90 Hennepin Avenue, Minneapolis, Minnesota 55401 (P.O. Box 291, Minneapolis 55480–0291)

Helena Branch
100 Neill Avenue, Helena, Montana 59601

Kansas City

925 Grand Blvd., Kansas City, Missouri 64198

Denver Branch
1020 16th Street, Denver, Colorado 80202 (Terminal Annex-P.O. Box 5228, Denver 80217)

Oklahoma City Branch
226 Dean A. McGee Avenue (P.O. Box 25129), Oklahoma City, Oklahoma 73125

Omaha Branch
2201 Farnam Street, Omaha, Nebraska 68102 (P.O. Box 3958, Omaha 68103)

Dallas

2200 North Pearl Street, Dallas, Texas 75201–2272 (P.O. Box 655906, Dallas 75265–5906)

El Paso Branch
301 East Main Street, El Paso, Texas 79901–1326 (P.O. Box 100, El Paso 79999–0100)

Houston Branch 1701 San Jacinto Street, Houston, Texas 77002–8215 (P.O. Box 2578, Houston 77252–2578)

San Antonio Branch
126 East Nueva Street, San Antonio, Texas 78204 (P.O. Box 1471, San Antonio 78295–1471)

San Francisco

101 Market Street, San Francisco, California 94105 (P.O. Box 7702, San Francisco 94120)

Los Angeles Branch
950 South Grand Avenue, Los Angeles, California 90015 (Terminal Annex-P.O. Box 2077, Los Angeles 90051)

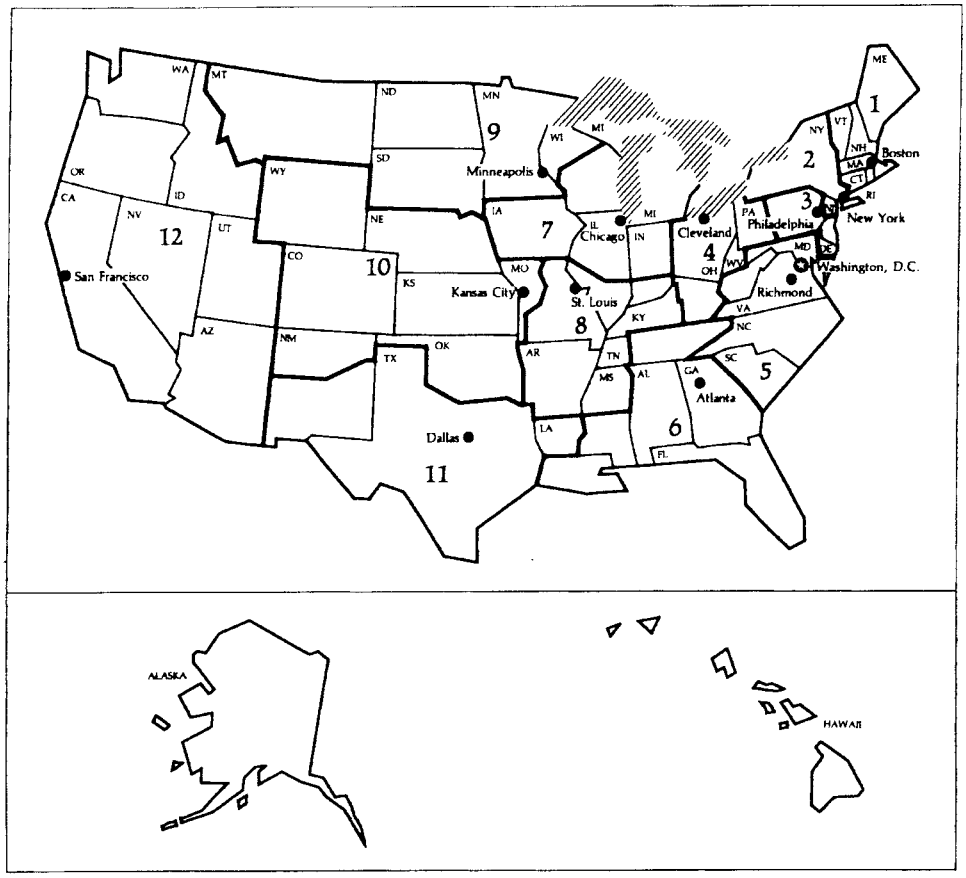
Portland Branch
915 S.W. Stark Street, Portland, Oregon 97025 (P.O. Box 3436, Portland 97208)

Salt Lake City Branch

* Additional offices of these Banks are located at Lewiston, Maine 04240; Windsor Locks, Connecticut 06096; East Rutherford, New Jersey 07073; Utica at Oriskany, New York 13424; Columbus Ohio 43216; Columbia, South Carolina 29210: Charleston, West Virginia 25328; Des Moines, Iowa 50306; Indianapolis, Indiana 46206; Milwaukee, Wisconsin 53201; and Peoria, Illinois 61601.

120 South State Street, Salt Lake City, Utah 84111 (P.O. Box 30780, Salt Lake City 84125)
Seattle Branch
1015 Second Avenue, Seattle, Washington 98104 (P.O. Box 3567, Seattle 98124)
Phoenix Processing Center
1550 N. 47th Avenue, Phoenix, Arizona 85043

Boundaries of Federal Reserve Districts



Legend

— Boundaries of Federal Reserve Districts

✪ Board of Governors of the Federal Reserve System

● Federal Reserve Bank Cities

By order, approved pursuant to authority delegated by the Board, effective July 12, 2001.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 01–17895 Filed 7–18–01; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act Meeting

TIME AND DATE: 10 a.m. (EDT), July 17, 2001.

PLACE: 4th Floor, Conference Room 4506, 1250 H Street, NW., Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Involvement of Board in a civil action.

CONTACT PERSON FOR MORE INFORMATION: Thomas J. Trabucco, Director, Office of External Affairs, (202) 942–1640.

Dated: July 17, 2001.

Salomon Gomez,

Associate General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 01–18251 Filed 7–17–01; 3:45 pm]

BILLING CODE 6760–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Public Health and Science; Office of Minority Health; Availability of Funds for a Cooperative Agreement for the HIV/AIDS Regional Resource Network Program

AGENCY: Office of the Secretary, Office of Public Health and Science, Office of Minority Health.

ACTION: Notice of availability of funds and request for applications for a cooperative agreement for the HIV/AIDS regional resource network program.

Program Title: HIV/AIDS Regional Resource Network Program.

OMB Catalog of Federal Domestic Assistance: The OMB Catalog of Federal

Domestic Assistance number for the HIV/AIDS Regional Resource Network Cooperative Agreement Program is 93.004.

Authority: This program is authorized under section 1707(e)(1) of the Public Health Service Act, as amended.

Purpose: The purpose of the HIV/AIDS Regional Resource Network Program is to increase the capacity of community-based organizations (CBOs), including small, minority CBOs, serving communities of color to provide prevention and early intervention services for poor, minority communities disproportionately impacted by HIV/AIDS and STDs. The program's goals are to:

- Facilitate the involvement of CBOs, including minority CBOs, serving communities of color in federal regional HIV/AIDS initiatives, planning, and networking; and
- Provide training and technical assistance to CBOs, including minority CBOs, serving communities of color to build their capacity to serve racial and ethnic minority communities with a high incidence of HIV.

The program is intended to demonstrate that by involving CBOs, including minority CBOs, serving communities of color in federal regional planning and networking efforts, the coordination, comprehensiveness, and quality of HIV/AIDS services to minority communities will be improved.

Eligible Applicants: Private, nonprofit organizations are eligible to apply for this cooperative agreement.

Note: Public organizations, universities and institutions of higher education are not eligible to apply for this cooperative agreement.

Organizations are not eligible to receive awards from more than one Office of Minority Health (OMH) program concurrently as the grant recipient. An organization may submit only one proposal under this announcement.

Availability of Funds: Approximately $1.2 million is expected to be available for one competitive award in FY 2001 for a 12-month period. Support may be requested for a total project period not to exceed 3 years.

The applicant chosen through the competitive review process:

- Will begin the HIV/AIDS Regional Resource Network Program on September 30, 2001.
- Will be able to apply for a noncompeting continuation award of up to $1.2 million for each of two additional years. After Year 1, funding is based on:

a. The amount of money available; and

b. Success or progress in meeting project objectives.

Note: For the noncompeting continuation awards, the grantee must submit continuation applications, written reports, and continue to meet the established program guidelines.

Use of Cooperative Agreement Funds: Budgets of up to $1.2 million total costs (direct and indirect) per year may be requested to cover costs of:

- Personnel.
- Consultants.
- Supplies.
- Equipment.
- Grant related travel.
- Other grant related costs.

Funds *may not* be used for:

- Medical treatment.
- Construction.
- Building alterations or renovations.

Note: All budget requests must be fully justified in terms of the proposed objectives and activities and include a computational explanation of how costs were determined.

Background

The mission of the Office of Minority Health (OMH) is to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help to address health disparities and gaps. The role of OMH is to serve as the focal point within HHS for service demonstrations, coalition and partnership building, and related efforts to address the health needs of racial and ethnic minorities. In keeping with this mission, the HIV/AIDS Regional Resource Network Program is to assist in addressing the HIV/AIDS issues facing minority communities disproportionately impacted by the epidemic.

In FY 1999, the Office of Public Health and Science, Office of Population Affairs, launched the HIV/AIDS Regional Resource Network Program as a two year program to conduct training and technical assistance activities for the purpose of increasing the capacity of small CBOs to provide prevention and early intervention services in poor, minority communities disproportionately impacted by HIV/AIDS, sexually transmitted diseases, and unwanted pregnancies. A demonstration project was developed to focus on improving the coordination, comprehensiveness, and quality of HIV/AIDS service provision by bringing CBOs serving communities of color into federal regional planning and networking efforts. Training and technical assistance was provided to high-risk communities to facilitate local and regional planning and prevention efforts, and create mechanisms for closer working relationships with federal regional offices. Regional Resource Consultants were placed in 5 of the HHS Regional Offices (New York, Atlanta, Dallas, Chicago, and San Francisco) to identify and network with HIV/AIDS organizations and agencies within their regions, to develop a regional directory of HIV/AIDS service organizations, and to oversee the distribution of capacity-building awards. In this FY 2001 cooperative agreement announcement, OMH is building on the efforts of the last two years and expanding the project to include all 10 HHS Regions.

Project Requirements:

The applicant must propose a model program to be carried out within each of the 10 HHS Regions that addresses the following goals:

- Facilitate the involvement of CBOs, including minority CBOs, serving communities of color in federal regional HIV/AIDS initiatives, planning, and networking; and
- Provide training and technical assistance to CBOs, including minority CBOs, serving communities of color to build their capacity to serve racial and ethnic minority communities with high incidence of HIV.

Note: A listing of the 10 HHS Regions and the Regional Health Administrator contacts is provided in the application kit.

Program Activities: In conducting activities to achieve the purpose of this cooperative agreement program, the grantee will be responsible for carrying out the activities listed under

1. Grantee Activities. The ten HHS Regional Offices and the OMH will be responsible for the activities listed under 2. HHS Regional Office Activities and 3. OMH Activities.

1. Grantee Activities:

a. Collaborate onsite with the 10 HHS Regional Offices to carry out the goals and activities of the cooperative agreement program. Such collaboration is to include assignment and supervision of a Regional Resource Consultant (RRC) in each regional office. The grantee is encouraged to involve the HHS Regional Offices in the selection of the RRCs;

b. Identify CBOs, including minority CBOs, serving communities of color which provide support and ancillary services to individuals and families affected and infected by HIV/AIDS;

c. Identify the training and technical assistance needs of these organizations and link them with appropriate HHS resources;

d. Establish networking relationships between the HHS Regional Offices and the CBOs and foster closer collaboration between these CBOs and federal, state and local governments;

e. Provide limited capacity building funds to eligible CBOs (NOTE: 40% of total cooperative agreement funds must be allocated for CBO capacity building awards);

f. Maintain regional resource directories of CBOs, including minority CBOs, serving communities of color that work with racial and ethnic communities in the area of HIV/AIDS programs or services; and

g. Develop a technical assistance/skills-building manual for use by targeted and other organizations serving communities of color to enhance their skills to serve racial and ethnic minority communities with high incidence of HIV.

2. HHS Regional Offices Activities:

a. Assist in the identification and selection of RRCs and provide in-kind support to the RRCs including office space, telephone usage, and Internet access;

b. Designate a federal employee in the regional office where the RRC is placed to oversee the consultant's activities (NOTE: Supervision of the RRCs is the responsibility of the grantee);

c. Participate in the review of regional capacity-building awards to eligible CBOs; and

d. Assist the RRCs in expanding their networking and planning relationships to include identifying tribal resources, coordinating efforts with HHS crisis response teams, and working with local and state prison systems to implement HIV screening, prevention, and treatment programs.

3. OMH Activities:

a. Provide assistance in the development of project methodologies and analysis as needed;

b. Provide assistance with linkages to federal agencies for technical assistance, training and other resources; and

c. Establish an Advisory Committee composed of members from HHS including the Regional Offices to make recommendations and provide advice and guidance in the implementation of program objectives.

Application Kit

- For this cooperative agreement, Form PHS 5161–1 (Revised July 2000 and approved by OMB under Control Number 0937–0189) must be used.
- An applicant is advised to pay close attention to the specific program guidelines and general instructions provided in the application kit.
- To get an application kit, write to: Ms. Karen Campbell, Grants Management Officer, Division of Management Operations, Office of Minority Health, Rockwall II Building, Suite 1000, 5515 Security Lane, Rockville, MD 20852.

Or call Karen Campbell at (301) 443–8441.

Where To Send Applications

Send the original and 2 copies of the complete grant application to: Ms. Karen Campbell, Grants Management Officer, Division of Management, Operations, Office of Minority Health, Rockwall II Building, Suite 1000, 5515 Security Lane, Rockville, MD 20852.

Application Deadline

To receive consideration, grant applications must be received by the OMH Grants Management Office by August 20, 2001. Applications will be considered as meeting the deadline if they are: (1) Received on or before the deadline date, or (2) postmarked on or before the deadline date and received in time for orderly processing. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. Applications submitted by facsimile transmission (FAX) or any other electronic format will not be accepted. Applications which do not meet the deadline will be considered late and will be returned to the applicant unread.

How to Get Help

In addition to contacting Karen Campbell for application kits, she may also be contacted for technical assistance on budget and business aspects of the application. For further explanations and answers to questions on programmatic aspects, contact: Ms. Cynthia H. Amis, Director, Division of Program Operations, Office of Minority Health, Rockwall II Building, Suite 1000, 5515 Security Lane, Rockville, MD 20852.

Or call: Cynthia Amis at (301) 594–0769.

For additional assistance contact the OMH Regional Minority Health Consultants listed in the grant application kit.

For health information contact the OMH Resource Center at 1–800–444–6472.

Review of Applications

- Applications will be screened upon receipt. Those that are judged to be incomplete, non-responsive, or nonconforming to the announcement will be returned without comment.
- An organization may submit no more than one proposal under this announcement.
- Organizations submitting more than one proposal will be deemed ineligible. The proposals will be returned without comment.
- Accepted applications will be reviewed for technical merit in accordance with PHS policies.
- Applications will be evaluated by an Objective Review Committee. Committee members are chosen for their expertise in minority health, their experience in technical assistance and capacity development, and their understanding of the unique health problems and related issues confronted by racial and ethnic minorities in the United States.

Application Review Criteria

The technical review of applications will consider the following 5 generic factors (including Background, Objectives, Methodology, Evaluation, and Management Plan), listed below in descending order of priority.

Factor 1: Methodology (35%)

- Appropriateness of proposed approach for regional collaboration including any established organizational linkages for providing training and technical assistance related to HIV/AIDS.
- Appropriateness of specific activities for providing training and technical assistance related to HIV/AIDS and capacity development.
- Logic and sequencing of the planned approaches in relation to the provision of HIV/AIDS training and technical assistance.

Factor 2: Evaluation (20%)

- Thoroughness, feasibility, and appropriateness of the evaluation design, data collection, and analysis procedures.
- Clear intent and plans to document the activities and their outcomes.
- Clear indication that the project will result in a model that can be replicated.

Factor 3: Background (15%)

- Established level of cultural competence and sensitivity to the issues of minority populations disproportionately impacted by HIV/AIDS.
- Expertise and understanding of HIV/AIDS prevention and treatment service delivery systems especially as related to HIV/AIDS care among minority populations.
- Demonstrated access to targeted organizations and experience in

working with CBOs, including minority CBOs, serving communities of color.

• Demonstrated experience in networking, planning, and implementing activities at a regional level.

• Demonstrated outcomes of past similar efforts/activities with the target population.

Factor 4: Objectives (15%)

• Merit of the objectives.

• Relevance to the program purpose and stated problem.

• Attainability in the stated time frames.

Factor 5: Management Plan (15%)

• Demonstrated knowledge/skills in organizational management, diversification of fiscal base, and organizational development; and ability to mobilize a strong training and technical assistance capacity onsite.

• Ability to plan and coordinate efforts at a regional level.

• Capability to manage and evaluate the project as determined by:

a. The qualifications of proposed staff or requirements for ''to be hired'' staff.

b. Staff level of effort.

c. Management experience of the applicant.

d. Clarity of the applicant's organizational chart.

Award Criteria

Funding decisions will be determined by the Deputy Assistant Secretary for Minority Health of the Office of Minority Health, and will take under consideration the recommendations and ratings of the Objective Review Committee.

Reporting and Other Requirements

General Reporting Requirements

A successful applicant under this notice will submit: (1) progress reports; (2) an annual Financial Status Report; and (3) a final progress report and Financial Status Report in the format established by the OMH, in accordance with provisions of the general regulations which apply under 45 CFR Part 74.51–74.52.

Public Health System Reporting Requirements

This program is subject to Public Health Systems Reporting Requirements. Under these requirements, a community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). 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 organizations within their jurisdictions.

Community-based nongovernmental 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); and (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 OMH.

State Reviews

This program is subject to the requirements of Executive Order 12372 which 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 available under this notice will contain a list of States which 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 SPOCs 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 of each affected State. The due date for State process recommendations is 60 days after the application deadline established by the OMH Grants Management Officer.

The OMH 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).

Additional Background Information

Disproportionate Effect of HIV/AIDS on Minorities

Statistics indicate that although advances have been made in the treatment of HIV/AIDS, this epidemic continues as a significant threat to the public health of the United States. Despite showing a decline in the past few years, HIV/AIDS remains a disproportionate threat to minorities. According to the CDC HIV/AIDS Surveillance Report December 1999 Year-end Edition (Vol. 11—Number 2), during the 1990s the epidemic shifted steadily toward a growing proportion of AIDS cases in African-Americans and Hispanics. In absolute numbers, African-Americans have outnumbered whites in new AIDS diagnoses and deaths since 1996 and the number of persons living with AIDS since 1998. While African-Americans and Hispanics respectively represent approximately 13% and 10% of the U.S. population, approximately 37% of the more than 733,000 reported total AIDS cases in 1999 were African-American and 18% are Hispanic.

In 1999, more African-Americans were reported with AIDS than any other racial/ethnic group. Of the total HIV infection cases reported through December 1999, 52% (64,299) were reported among African-Americans, 38% (46,277) were reported among whites, and 8% (9,296) were reported among Hispanics. Among women and children with AIDS, African-Americans have been especially affected, representing 63% of all women reported with AIDS in 1999 and 65% of reported pediatric AIDS cases in 1999. During 1999, the rate of new AIDS cases per 100,000 population in the U.S. was 84.2 among African-Americans, 34.6 among Hispanics, 9.0 among whites, 11.3 among American Indians/Alaska Natives, and 1.4 among Asians/Pacific Islanders.

The recent CDC Morbidity and Mortality Weekly Report (June 1, 2001/ Volume 50, Number 21) describes the changes in the characteristics of persons with AIDS since 1981 with the greatest impact of the epidemic among men who have sex with men (MSM) and among racial/ethnic minorities. The report presents data on the number and percentage of persons with AIDS by race/ethnicity since the first AIDS cases were reported in the U.S. in June 1981. These data show overall increases in AIDS cases among minority populations from 1981 to 2000: African-Americans (25.5% to 44.9%); Hispanics (14% to 19.7%); Asian/Pacific Islanders (0.6% to 0.8%), and American Indians/Alaska Natives (0.1% to 0.4%). In contrast, the data show a decrease in AIDS cases among whites (59.7% to 34%) for the same period. The report also points to a resurgent HIV epidemic among men who have sex with men (MSM), particularly among young minority males. The prevalence of HIV infection was higher among African-Americans

(14.1%), Hispanics (6.9%), and American Indians/Alaska Natives (6.7%) than among whites (3.3%) and Asian/Pacific Islanders (3%).

Healthy People 2010: The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a PHS-led national activity announced in January 2000 to eliminate health disparities and improve years and quality of life. HIV/AIDS is one focus area of Healthy People 2010. More information may be found on the Healthy People 2010 web site: *http://www.health.gov/healthypeople,* and copies of the document may be downloaded. Copies of the *Healthy People 2010: Volumes I and II* can be purchased by calling (202) 512–1800 (cost $70.00 for printed version; $19.00 for CD–ROM). Another reference is the *Healthy People 2010 Review-1998–99.* For 1 free copy of the *Healthy People 2010 Review-1998–99,* contact: The National Center for Health Statistics, Division of Data Services, 6525 Belcrest Road, Room 1064, Hyattsville, MD 20782, or telephone at (301) 458–4636.

Ask for HHS Publication No. (PHS) 99–1256. This document may also be downloaded from the NCHS web site: http://www.cdc.gov/nchs.

Definitions

For purposes of this cooperative agreement announcement, the following definitions are provided:

Community-Based Organization—Private, nonprofit organizations *and* public organizations that are representative of communities or significant segments of communities where the control and decision-making powers are located at the community level.

Minority Community-Based Organization—Private nonprofit community-based organizations or local affiliates of national organizations that have a governing board composed of 51 percent or more racial/ethnic minority members and a significant number of minorities employed in key program positions.

Minority Populations—

- American Indian or Alaska Native.
- Asian.
- Black or African American.
- Hispanic or Latino.
- Native Hawaiian or Other Pacific Islander.

(Revision to the Standards for the Classification of Federal Data on Race and Ethnicity, **Federal Register**, Vol. 62, No. 210, pg. 58782, October 30, 1997.)

Dated: July 13, 2001.

Nathan Stinson, Jr.,

Deputy Assistant Secretary for Minority Health.

[FR Doc. 01–18070 Filed 7–18–01; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Meeting: Secretary's Advisory Committee on Genetic Testing

Pursuant to Public Law 92–463, notice is hearby given of the tenth meeting of the Secretary's Advisory Committee on Genetic Testing (SACGT), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to 4:30 p.m. on August 17, 2001 at the National Institutes of Health, Building 31, C Wing, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892. The meeting will be open to the public with attendance limited to space available.

The Committee will discuss two major topics: (1) The outcomes and discussion of an outreach meeting convened by the Data Work Group on a proposed pre-market review template, post-market data collection efforts, and proposed Q & A for genetic tests for health providers; and (2) issues related to genetics education for health professionals, including a presentation from the National Coalition for Health Professional Education in Genetics. Time will be provided for public comment and interested individuals should notify the contact person listed below.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGT to advise and make recommendations to the Secretary through the Assistant Secretary for Health on all aspects of the development and use of genetic tests. The SACGT is directed to (1) recommended policies and procedures for the safe and effective incorporation of genetic technologies into health care; (2) assess the effectiveness of existing and future measures for oversight of genetic tests; and (3) identify research needs related to the Committee's purview.

The draft meeting agenda and other information about SACGT will be available at the following web site: *http://www4.od.nih.gov/oba/sacgt.htm* Individuals who wish to provide public comments or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACGT Executive Secretary, Ms. Sarah Carr, by telephone at 301–496–9838 or E-mail at *sc112c@nih.gov.* The SACGT office is located at 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892.

Dated: July 9, 2001.

Sarah Carr,

Executive Secretary, SACGT.

[FR Doc. 01–18042 Filed 7–18–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01190]

Human Immunodeficiency Virus (HIV) Prevention Intervention Research Studies—Prevention for HIV-Positive Persons; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program for the prevention for HIV-positive persons. This program addresses the ''Healthy People 2010'' focus area of HIV.

The purpose of the activity is to generate effective prevention service models designed for HIV-infected persons, to be delivered at HIV care settings.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: Title 2 of the United States Code, chapter 26, section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that

engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately $750,000 is available in FY 2001 to fund approximately three to five awards. It is expected that the average award will be $250,000, ranging from $150,000 to $350,000. It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

1. Use of Funds

Funds are awarded for a specifically defined purpose and may not be used for any other purpose or program. Funds may be used to support personnel and to purchase equipment, supplies, and services directly related to project activities. Funds may not be used to supplant State or local funds available for HIV Prevention. Funds may not be used to provide direct medical care.

2. Funding Preferences

Preference will be given to applicants with geographic and population risk group diversity.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

a. Develop the prevention intervention, research study protocol and data collection forms.

b. Plan and conduct project activities such as, enrolling care sites into comparison (or control) and intervention groups; implementing the prevention intervention; and collecting and analyzing data to evaluate the prevention intervention.

c. Where necessary, build and maintain a coalition to adequately implement the program and research design.

d. Where appropriate, obtain the participation of state and local professional associations and healthcare providers and institutions in serving, diagnosing, or providing treatment and care for persons with HIV/AIDS.

e. Promote the adoption of effective prevention services for HIV-infected persons in care settings other than those participating in the study by: (1) Providing data and ongoing assistance to community planning groups; (2) disseminating data through publications and presentations.

f. Participate in project planning and implementation meetings with other collaborators, when appropriate.

g. Establish procedures to maintain the rights and confidentiality of all study participants.

h. Identify, recruit, obtain informed consent from participants (when appropriate), and enroll an adequate number of study participants as determined by study protocol and the program requirements. The protocol must be submitted to the local Institutional Review Boards (IRB) for approval.

i. Share data and specimens (when appropriate) with other collaborators to answer specific research questions.

j. Participate in multi-site data analysis and presentation and publication of research findings with collaborators, when appropriate.

2. CDC Activities

a. Provide technical assistance, as needed, in refining the proposed intervention.

b. As needed, assist in designing a data management system and data analysis and dissemination of findings.

c. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to follow them in laying out your program plan. The narrative should be no more than 25 pages double-spaced, printed on one side, with one inch margins, and unreduced font.

The narrative should consist of, at a minimum, a Plan, Objectives, Methods, Evaluation and Budget.

F. Submission and Deadline

Submit the original and five copies of PHS form 398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are available at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm

On or before August 27, 2001, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date; or

2. Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late: Applications which do not meet the criteria in 1. or 2. above will not be considered and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an objective review group appointed by CDC.

1. Background, Understanding of Problem and Objectives (10 Points)

To the extent to which the applicant—

a. Demonstrates knowledge of literature pertinent to the proposed program and its goals. Demonstrates an understanding of how prevention models developed for high-risk individuals should be adapted, as suggested by theory or research, to customize the service for HIV infected persons. (5 points)

b. Provides a compelling argument for justifying the care setting in which program will be implemented (patient load, lack of available prevention services, etc.). In addition, provide information on high HIV prevalence and incidence, and opportunities for evaluating prevention services designed for HIV infected persons in various HIV care settings. (5 points)

2. Demonstrating the Quality of Proposed Prevention Program (15 Points)

To the extent to which the applicant—

a. Demonstrates adequacy of proposed program to address the purpose stated in the background section: Reduction in unprotected sex and/or needle sharing with HIV negative partners and partners of unknown status. (Disclosure of serostatus and adherence to therapy are acceptable but not required as additional outcomes). (8 points)

b. Presents a program which adequately incorporates into the prevention model organizational and personnel factors which accelerate adoption and proper implementation by

the care organizations specified in the application. (7 points)

3. Demonstrating the Appropriateness of Research Design To Evaluate the Proposed Program (30 points):

To the extent to which the applicant—

a. Presents an overall research design which can generate reasonably certain conclusions about the effects of the proposed program; and which includes appropriate design elements such as: Outcome measures taken at pre-intervention, post-intervention and follow-up; process measures; control or comparison group(s). (10 points)

b. Presents reliable and valid measures to gauge effectiveness at three levels: Organizational adoption (ability and willingness of the service organization to provide sustained support); adoption by care personnel (acceptance and use by the individual service providers); reduction in risk behaviors by clients. (10 points)

c. In addition, applications will be evaluated on the degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (10 points)

1. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

2. The proposed justification when representation is limited or absent.

3. A statement as to whether the design of the study is adequate to measure differences when warranted.

4. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

4. Demonstrating the Ability To Implement the Intervention and the Research Design (45 Points)

a. Demonstrates the extent to which the applicant has the necessary skills and resources needed for both program and research design implementation. In cases where a collaboration is necessary between different organizations, demonstrates the ability to put together the collaboration necessary for adequately implementing the program and the research design. Demonstrates the degree of commitment from non-lead organizations to the project and explains how the lead organization intends to maintain this commitment. Letters of support from all collaborating organizations are the required minimum. (10 points)

b. Identifies the technical assistance and training needs required for the proper implementation of the prevention service and the research protocol, and presents a plan that ensures that these needs will be met. (5 points)

c. Specifies methods for careful verification that the proposed intervention is actually being implemented. (5 points)

d. Specifies a plan for tracking participants and ensuring successful follow-up. (5 points)

e. Presents a plan for carrying out the program and research activities. (5 points)

f. Demonstrates experience and expertise in conducting similar prevention programs and research. (15 points)

6. Budget (Not Scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the intent of the announcement.

7. Human Subjects (Not Scored)

Does the application adequately address the requirements of 45 CFR part 46 for the protection of human subjects? (Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks are so inadequate as to make the entire application unacceptable.)

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original and two copies of:

1. Annual progress reports to be submitted with subsequent continuation applications;

2. Financial status report, no more than 90 days after the end of the budget period;

3. Final financial report and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the announcement.

AR–1 Human Subjects Requirements

AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR–4 HIV/AIDS Confidentiality Provisions

AR–5 HIV Program Review Panel Requirements

AR–7 Executive Order 12372 Review

AR–9 Paperwork Reduction Act Requirements

AR–10 Smoke-Free Workplace Requirements

AR–11 Healthy People 2010

AR–12 Lobbying Restrictions

AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act sections 317 (42 U.S.C. 241(a) and 247b); 301 (42 U.S.C. 241); and 311 (42 U.S.C. 243), as amended. The Catalog of Federal Domestic Assistance number is 93.941.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address http://www.cdc.gov Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documentation, business management technical assistance may be obtained from: James Masone, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Mailstop E–15, Atlanta, GA 30341–4146 Telephone: (770) 488–2736, Email address: zft2@cdc.gov.

For program technical assistance, contact: Cassandra Walker, MPH, Acting Deputy Chief, Prevention Services Research Branch, Division of HIV/AIDS Prevention, Surveillance & Epidemiology, National Center for HIV, STD, TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, Mailstop E–46, Atlanta, GA 30333, Telephone: (404) 639–6191, Email address: cwalker5@cdc.gov.

Dated: July 13, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–18049 Filed 7–18–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Initial Review Group, Subcommittee C—Basic & Preclinical.

Date: July 31–August 2, 2001.

Time: 4 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Michael B. Small, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8040, Bethesda, MD 20892, 301/402–0996.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–18037 Filed 7–18–01; 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 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 Child Health and Human Development Special Emphasis Panel.

Date: July 31, 2001.

Time: 10 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Governor's House, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Anne Krey, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Rm. 5E03, Bethesda, MD 20892, 301–435–6908.

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. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: July 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–18035 Filed 7–18–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, July 18, 2001.

Date: July 18, 2001.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: 6100 Executive Blvd., Room 5E01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Gopal M. Bhatnagar, PhD, Scientific Review Administrator, Divison of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, PHS, DHHS, 9000 Rockville Pike, 6100 Bldg., Room 5E01, Bethesda, MD 20891, (301) 496–1485.

This notice is being published less than 15 days prior to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93–209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: July 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–18036 Filed 7–18–01; 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 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 Child Health and Human Development Special Emphasis Panel.

Date: July 18, 2001.
Time: 3 p.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: 6100 Executive Blvd., Room 5E01, Rockville, MD 20852 (Telephone Conference Call).
Contact Person: Gopal M. Bhatnagar, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, PHS, DHHS, 9000 Rockville Pike, 6100 Bldg., Room 5E01, Bethesda, MD 20892, (301) 496–1485.
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. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: July 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–18038 Filed 7–18–01; 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 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 Child Health and Human Development Special Emphasis Panel.
Date: July 30, 2001.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: 1775 Rockville Pike, Rockville, MD 20852.
Contact Person: Hameed Khan, PhD, Scientific Review Administratorator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Room 5E01, Bethesda, MD 20892, (301) 496–1485.
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. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: July 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–18040 Filed 7–18–01; 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 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 Child Health and Human Development Special Emphasis Panel ''Cooperative Multicenter Research Network To Test Glucose Sensors in Children with Type 1 Diabetes Mellitus.
Date: August 10, 2001.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Ritz Carlton Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.
Contact Person: Norman Chang, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, National Institutes of Health, 6100 Executive Blvd., Room 5E03, Bethesda, MD 20892, (301) 496–1485.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: July 12, 2001.

LaVerene Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–18041 Filed 7–18–01; 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 Site Visit.
Date: July 29–31, 2001.
Time: July 29, 2001, 8:30 p.m. to 11 p.m.
Agenda: To review and evaluate grant applications.
Place: Best Western Inn Towner, 2424 University Avenue, Madison, WI 53705.
Time: July 30, 2001, 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Best Western Inn Towner, 2424 University Avenue, Madison, WI 53705.
Time: July 31, 2001, 8 a.m. to 12 p.m.
Agenda: To review and evaluate grant applications.
Place: Best Western Inn Towner, 2424 University Avenue, Madison, WI 53705.
Contact Person: Merlyn M. Rodrigues, MD, PhD, Medical Officer/SRA, National Library of Medicine, Extramural Programs, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20894.
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. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: July 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–18039 Filed 7–18–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4579–FA–10]

Announcement of Funding Awards for Fiscal Year 2000 Research and Technology Unsolicited Proposals

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this document notifies the public of funding awards for Fiscal Year 2000 Research and Technology unsolicited proposals. The purpose of this document is to announce the names and addresses of the organizations that have been awarded cooperative agreements based on their submission of unsolicited proposals for research funding.

FOR FURTHER INFORMATION CONTACT: Patrick J. Tewey, Director, Budget, Contracts and Program Control Division, Office of Policy Development and Research, Room 8230, 451 7th Street, SW, Washington, DC 20410, telephone (202) 708–1796, extension 4098. To provide service for persons who are hearing-or-speech-impaired, this number may be reached via TTY by dialing the Federal Information Relay Service on 1–800–877–TTY, 1–800–877–8339, or 202–708–1455. (Telephone number, other than ''800'' TTY numbers are not toll free.)

SUPPLEMENTARY INFORMATION: The VA/HUD and Independent Agencies Appropriation Act of 2000 (Pub. L. 106–74) provided $45,000,000 in Research and Technology funds for contracts, grants and necessary expenses of programs and studies relating to housing and urban problems. HUD's Office of Policy Development and Research administers the Research and Technology funds. The majority of HUD's Research and Technology funding is awarded through competitive solicitations. The unsolicited proposal is another method used by HUD to fund research and development. An unsolicited proposal is submitted to support an idea, method or approach by individuals and organizations solely on the proposer's initiative. Funding of unsolicited proposals is considered a noncompetitive action. An unsolicited proposal demonstrates a unique and innovative concept or a unique capability of the submitter, offers a concept or service not otherwise available to the Government and does not resemble the substance of a pending competitive action. All unsolicited proposals and the resulting award of cooperative agreements include substantial cost sharing on the part of the submitter/awardee.

The Catalog of Federal Domestic Assistance for this program is 14.506

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), the Department is publishing details concerning the recipients of funding awards, as follows:

List of FY2000 Awardees for Cooperative Agreements

Fulton Montgomery Community College, Anna D. Weitz, 2805 State Hwy. 67, Johnson, NY 12095–3790, Grant #H–21250CA, ''Revitalization through Technology and Education-Based Institution'', Total Amount $100,000, Date Awarded 09/29/00.

University Consortium for Geographic Information Science, Susan Jampoler, Spinks Ferry Road, Leesburg, VA 20176–5631, Grant #H–21260CA, ''Global Urban Quality'', Total Amount $240,000, Date Awarded 09/25/00.

Canisius College, Dr. Marion Meyers, 2001 Main St. Buffalo, NY 14208, Grant #H–21264CA, ''State of the Cities Data Systems (SOCDS) Improvements-Government Finances Data'', Total Amount $134,065, Date Awarded 09/06/00.

National League of Cities Institute, Emily Stem, 1301 Pennsylvania Avenue, NW., Washington, DC 20004, Grant #H–21218CA, ''Municipalities in Transition: A Panel Study for Economic Demographic and other Transition in Urban Areas'', Total Amount $98,657, Date Awarded 06/30/00.

Carnegie Mellon University, Susan Burkett, Office of Sponsored Research, 5000 Forbes Avenue Cyert Hall 102, Pittsburgh, PA 15213, Grant #H–21252CA, ''Inter and Intra Metropolitan Migration'', Total Amount $130,418, Date Awarded 07/27/00.

Manpower Demonstration Research Corporation, Judith M. Gueron, 16 East 34 Street, New York, NY 10016–4326, Grant #H–21042CA, ''Jobs Plus Community Revitalization Initiative for Public Housing Families'', Total Amount $1,700,000, Date Awarded 04/01/00.

American Planning Association, Frank S. So, 122 South Michigan Avenue, Suite 1600, Chicago, IL 60603–6107, Grant #H–21213CA, ''Regional Approaches to Affordable Housing'', Total Amount $185,000, Date Awarded 04/03/00.

PolicyLink, Angela Glover Blackwell, 1010 Broadway, Oakland, CA, Grant #H–21271CA, ''National Community Equity Mechanisms (CEM)'', Total Amount $60,000, Date Awarded 09/29/00.

Urban Land Institute, Rachelle Levitt, 1025 Thomas Jefferson Street, NW., Suite 500 West, Washington, DC 20007–5201, Grant #H–21270CA, ''Implementing Solutions to Barriers to Urban Infill'', Total Amount $350,000, Date Awarded 09/27/00.

Lincoln Institute of Land Policy, Carolyn Ruhe, 113 Brattle Street, Cambridge, MA 02138, Grant #H–21210CA, ''A National Symposium on Land Market Monitoring'', Total Amount $25,000, Date Awarded 04/06/00.

Partners For Livable Communities, Sue Coppa, 1429 21st Street, NW., Washington, DC 20036, Grant #H–21206CA, ''Crossing the Line, Bridging the Divide'', Total Amount $25,000, Date Awarded 11/01/99.

Manufactured Housing Research Alliance, Emanuel Levy, 220 West 93rd Street, 11th Floor, New York, NY 10025, Grant #H–21212CA, ''Manufactured Housing Cooperative Research'', Total Amount $500,000, Date Awarded 07/05/00.

The Urban Institute, Avis Vidal, 2100 M. Street, NW., Washington, DC 20037, Grant #H–21214CA, ''The Role of Faith-Based Organization in Community Development'', Total Amount $16,022, Date Awarded 05/25/00.

National Hispanic Housing Coalition, Ruth Pagani, 318 Fourth Street, NE., Washington, DC 20002, Grant #H–21235CA, ''A Study of the Determinants of Hispanic Participation in Federally-Funded Housing Programs'', Total Amount $125,000, Date Awarded 06/21/00.

Urban Land Institute, Rachelle Levitt, 1025 Thomas Jefferson Street, NW., Suite 500 West, Washington, DC 20007–2501, Grant #H–21203CA, ''Overcoming Obstacles to Infill Housing Development'', Total Amount $45,000, Date Awarded 09/27/00.

National Trust For Historic Preservation, Richard Moe, 1785 Massachusetts Avenue, NW., Washington, DC 20036, Grant #H–21274CA, ''Open Space Co-Oping''

Total Amount $182,680, Date Awarded 9/29/00.

National Governors' Association Center for Best Practice, Raymond Scheppach, 444 North Capitol St. NW., Suite 267, Washington, DC 20001–1512, Grant #H–21290CA, ''Where Do We Grow From Here?'', Total Amount $200,000, Date Awarded 09/29/00.

U.S.-Mexico Chamber of Commerce, Albert C. Zapanta, 1300 Pennsylvania Avenue, NW., Suite 270, Washington, DC 20004–3021, Grant #H–21251CA, ''HUD and Business Roundtable on the Southwest Borders'', Total Amount $50,364, Date Awarded 08/17/00.

The Regents of the University of California, Bobbie M. Velasquez, University of California-San Diego, 9500 Gilman Drive, Mail Code 0934, La Jolla, CA 92093–0934, Grant #H–21240CA, ''California-Baja California Border Conference'', Total Amount $33,391, Date Awarded 09/26/00.

Philadelphia Housing Authority, Carl Greene, 12 South 23rd Street, Philadelphia, PA 19103, Grant #H–21273CA, ''Impact of Tenant Based Section 8 and Housing Voucher Concentrations on Real Estate Market Values in the City of Philadelphia'', Total Amount $50,000, Date Awarded 09/26/00.

Woodrow Wilson International Center for Scholars, Dean W. Anderson, One Woodrow Wilson Plaza, 1300 Pennsylvania Avenue, NW, Washington, DC 20004–3027, Grant #H–21239CA, ''The International Research Monitor'', Total Amount $100,000, Date Awarded 09/27/00.

National Coalition for Asian Pacific American Community Development, Christopher Kui, Chairman, 108–110 Norfolk Street, New York, NY 10002, Grant #H–21234SG, ''API Housing and Community Needs Study'', Total Amount $10,000, Date Awarded 5/22/00.

NAHB Research Center, Lisa K. Bowles, 400 Prince Georges Boulevard, Upper Marlboro, MD 20772, Grant #H–21205CA, ''ToolBase Services: The Building Industry's Information Infrastructure'', Total Amount $749,966, Date Awarded 03/01/00.

NAHB Research Center, Lisa K. Bowles, 400 Prince George's Boulevard, Upper Marlboro, MD 207742–8731, Grant #H–21217CA, ''Planning and Designing of Research Homes'', Total Amount $500,000, Date Awarded 06/27/00.

NAHB Research Center, Lisa K. Bowles, 400 Prince George's Boulevard, Upper Marlboro, MD 20772–8731, Grant #H–21216CA, ''Innovative Structural Materials and Design Research for Residential Construction'', Total Amount $250,000, Date Awarded 06/20/00.

The American Society of Civil Engineers/Institute For Business & Home Safety, Thomas R. McLane, 1801 Alexander Bell Drive, Reston, VA 20192–4400, Grant #H–21211CA, ''America's Ten Most Wanted'', Total Amount $24,500, Date Awarded 07/09/00.

North America Steel Framing Alliance, Donald R. Moody, 1726 M Street, NW., Suite 601, Washington, DC 20036–4523, Grant #H–21248CA, ''Corrosion of Galvanized Fasteners Used in Cold-Formed Steel Framing'', Total Amount $37,400, Date Awarded 09/26/00.

North America Steel Framing Alliance, Donald R. Moody, 1726 M Street, NW., Suite 601, Washington, DC 20036–4523, Grant #H–21247CA, ''Prescriptive Details for Hybrid Cold-Formed Steel/Wood Framing'', Total Amount $124,493, Date Awarded 09/26/00.

Dated: July 12, 2001.

Lawrence L. Thompson,

General Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 01–18076 Filed 7–18–01; 8:45 am]

BILLING CODE 4210–29–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4630–FA–37]

Announcement of Funding Awards for the Rural Housing and Economic Development Program; Fiscal Year 2001

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the Super Notice of Funding Availability (SuperNOFA) for the Rural Housing and Economic Development Program. This announcement contains the names of the awardees and the amounts of the awards made available by HUD.

FOR FURTHER INFORMATION CONTACT: Jackie W. Mitchell, Director, Office of Rural Housing and Economic Development, Office of Economic Development, Office of Community Planning and Development, 451 7th Street, SW, Washington, DC 20410; telephone (202) 708–2290 (this is not a toll-free number). Hearing-and speech-impaired persons may access this number via TTY by calling the Federal Relay Service toll-free at 1–800–877–8339. For general information on this and other HUD programs, call Community Connections at 1–800–998–9999 or visit the HUD Website at *http://www.hud.gov.*

SUPPLEMENTARY INFORMATION: The Rural Housing and Economic Development program was authorized by the Department of Veteran's Affairs, Housing and Urban Development and Independent Agencies Appropriations Act of 1999. The competition was announced in the SuperNOFA published February 26, 2001 (66 FR 12187). Applications were rated and selected for funding on the basis of selection criteria contained in that Notice.

The Rural Housing and Economic Development Program is designed to build capacity at the State and local level for rural housing and economic development and to support innovative housing and economic development activities in rural areas. Eligible applicants are local rural non-profit organizations, community development corporations, Indian tribes, and State housing finance agencies. The funds made available under this program will be awarded competitively, through a selection process conducted by HUD in consultation with the United States Department of Agriculture (USDA).

Prior to the rating and ranking of this year's applications, Butler County Rural Electric Cooperative in Allison, Iowa was awarded $600,000 as a result of a funding error during the previous year's funding. For the Fiscal Year 2001 competition, a total of $24,042,487 was awarded to 111 projects nationwide.

The Catalog of Federal Domestic Assistance number for this program is 14.250.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987. 42 U.S.C. 3545), the Department is publishing the grantees and amounts of the awards in Appendix A to this document.

Dated: July 13, 2001.

Roy A. Bernardi,

Assistant Secretary for Community Planning and Development.

Appendix A

FY 2001 Rural Housing and Economic Development Competitive Grants

Applicant	State	City	Grant
Alabama Rural Heritage Foundation, Inc	AL	Thomaston	$400,000
Alabama Mayors Corporation for Economic, Cultural and Educational Development	AL	Birmingham	398,768
South East Alabama Self-Help Association, Inc	AL	Tuskegee	148,797
United Presbyterians of Wilcox County, Inc	AL	Catherine	150,000
Ciunerkiuvik Corporation	AK	Saint Marys	50,000
Tingit-Halda Regional Housing Authority	AK	Juneau	70,658
Bee Hoogan Shelter Foundation, Inc	AZ	Fort Defiance	150,000
Chicanos Por La Causa Tucson	AZ	Tucson	400,000
PPEP Microbusiness and Housing Development Corp	AZ	Tucson	400,000
United Housing and Educational Development	AZ	Tucson	150,000
Yavapai-Apache Nation	AZ	Camp Verde	140,788
Yavapai-Apache Nation	AZ	Camp Verde	399,788
North Fork Community Development Corporation	CA	North Fork	150,000
Self Help Enterprises	CA	Visalia	400,000
Walking Shield American Indian Society, Inc	CA	Tustin	400,000
Colorado Rural Housing Development Corporation	CO	Westminster	100,000
Region 10 League for Economic Assistance & Planning, Inc	CO	Montrose	100,000
Southwest Community Resources, Inc	CO	Durango	49,350
Everglades Community Association, Inc	FL	Florida City	400,000
Homes in Partnership, Inc	FL	Apopka	150,000
Housing Development Corporation of Macon County	GA	Montezuma	150,000
Southwest Georgia Housing Development Corporation	GA	Cuthbert	110,425
Southwest Georgia United Empowerment Zone, Inc	GA	Cordele	149,400
Sapelo Island Cultural & Revitalization Society	GA	Sapelo Island	149,100
Na'alehu Theatre	HI	Na'alehu	89,780
Coeur d'Alene Tribe	ID	Worley	150,000
Downtown Hays Development Corporation	KS	Hays	100,000
Original Town of Liberal Revitalization, Inc	KS	Liberal	150,000
Kentucky Mountain Housing Development Corporation, Inc	KY	Manchester	100,000
Low Income Housing Coalition of Floyd County	KY	Prestonsburg	125,505
Louisiana Department of Economic Development	LA	Baton Rouge	400,000
Northlake Community Development Corporation	LA	Hammond	150,000
Project 2000, Inc	LA	Hammond	75,000
Eastern Maine Development Corporation	ME	Bangor	100,000
Penobscot Indian Nation	ME	Old Town	399,581
Red Lake Housing Authority	MN	Red Lake	400,000
Energy Related Homes of Mississippi, Inc	MS	Jackson	150,000
Mississippi Action for Community Education, Inc	MS	Greenville	150,000
Mississippi Home Corporation	MS	Jackson	323,388
Quitman County Development Organization	MS	Marks	150,000
Southeastern Development Opportunities, Inc	MS	Shelby	120,450
Action for Eastern Montana, Inc	MT	Glendive	149,939
Blackfeet Tribe	MT	Browning	150,000
Confederated Salish & Kootenai Tribes	MT	Pablo	400,000
Fort Belknap Indian Community	MT	Harlem	400,000
Fort Belknap Indian Community	MT	Harlem	150,000
Heritage Institute	MT	Glasgow	399,731
Heritage Institute	MT	Glasgow	149,284
Ktunaxa Community Development Corporation	MT	Elmo	128,139
Santee Sioux Tribe	NE	Niobrara	150,000
West Central Nebraska Development District, Inc	NE	Ogallala	90,000
Women's Rural Entrepreneurial Network—WREN	NH	Bethlehem	100,000
Fallon Paiute-Shoshone Tribal Housing Department	NV	Fallon	400,000
Fallon Paiute-Shoshone Tribal Housing Department	NV	Fallon	150,000
New Mexico Mortgage Finance Agency	NM	Albuquerque	400,000
Eastern Plains Housing Development Corporation	NM	Clovis	150,000
Community Action Agency of SNM, Inc	NM	Las Cruces	400,000
Community Action Agency of SNM, Inc	NM	Las Cruces	150,000
Mesilla Valley Economic Development Alliance	NM	Las Cruces	400,000
Mesilla Valley Economic Development Alliance	NM	Las Cruces	150,000
Pojoaque Housing Corporation	NM	Santa Fe	150,000
San Juan Pueblo	NM	San Juan Pueblo	150,000
Zuni Indian Tribe	NM	Zuni	150,000
Northwestern Housing Enterprises, Incorporated	NC	Boone	150,000
Community Developers of Beaufort-Hyde, Inc	NC	Belhaven	150,000
Native Way Opportunity, Community Development Corporation, Inc	NC	Hollister	149,560
The Way Station	OH	Columbiana	149,230
WSOS Community Action Commission	OH	Fremont	50,000
Jackson-Vinton Community Action, Inc	OH	Wellston	150,000
Housing Authority of the Choctaw Nation of Oklahoma	OK	Hugo	400,000

Applicant	State	City	Grant
Housing Authority of the Choctaw Nation of Oklahoma	OK	Hugo	150,000
Langston Community Development Corporation	OK	Langston	150,000
Alabama-Quassarte Tribal Town	OK	Muskogee	59,920
Pawnee Nation of Oklahoma	OK	Pawnee	399,700
Morning Star Foundation of the Pawnee Nation, Inc	OK	Sand Springs	150,000
Cherokee Nation	OK	Tahlequah	400,000
International Bio Oxidative Medicine Foundation	OR	Grants Pass	150,000
Confederated Tribes of the Umatilla Indian Reservation	OR	Pendleton	400,000
Lawyers' Campaign for Equal Justice	OR	Portland	100,000
Redevelopment Authority of Fayette County	PA	Uniontown	400,000
Ceiba Housing and Economic Development Corporation	PR	Ceiba	150,000
Williamsburg Enterprise Community Commission, Inc	SC	Kingstree	95,900
Oglala Sioux Tribe Partnership	SD	Pine Ridge	400,000
Oglala Sioux Tribe Partnership	SD	Pine Ridge	100,000
Oti Kaga, Inc	SD	Eagle Butte	100,000
Sicangu Wicoti Awanyakape Corporation	SD	Rosebud	400,000
Legal Aid of Central Texas, Inc	TX	Austin	150,000
Community Development Corporation of Brownsville	TX	Brownsville	400,000
Neighborhood Housing Service of Dimmit County, Inc	TX	Carrizo Springs	400,000
El Paso Collaborative For Community & Economic Development	TX	El Paso	400,000
South Plains Community Action Association, Inc	TX	Levelland	150,000
Walker-Montgomery Community Development Corporation	TX	New Waverly	150,000
Organizacion Progresiva De San Elizario	TX	San Elizario	150,000
Center for Economic Opportunities	TX	San Juan	400,000
Futuro Communities, Inc	TX	Uvalde	99,956
Navajo Utah Commission	UT	Montezuma Creek	400,000
Surry Community Development and Housing Corporation	VA	Surry	130,300
Gilman Housing Trust, Inc	VT	Newport	150,000
Lummi Indian Nation	WA	Bellingham	400,000
Port Gamble S'Klallam Housing Authority	WA	Kingston	137,968
Upper Valley Mend	WA	Leavenworth	150,000
North Columbia Action Council	WA	Moses Lake	150,000
Confederated Tribes of the Colville Reservation	WA	Nespelem	400,000
Willapa Community Development Association	WA	Raymond	150,000
The Jamestown S'Klallam Tribe	WA	Sequim	400,000
Office of Rural and Farmworker Housing	WA	Yakima	150,000
Impact Seven, Inc	WI	Almena	400,000
Ho-Chunk Nation	WI	Black River Falls	400,000
Ho-Chunk Nation	WI	Black River Falls	102,082
Mid-Ohio Valley Regional Council	WV	Parkersburg	50,000
Northern Arapaho Tribe	WY	Ethete	150,000

[FR Doc. 01–18075 Filed 7–18–01; 8:45 am]
BILLING CODE 4210–29–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Colusa Basin Drainage District's Integrated Resources Management Program for Flood Control in the Colusa Basin in Glenn, Colusa, and Yolo Counties, CA

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability of the Final Programmatic Environmental Impact Statement/Final Programmatic Environmental Impact Report (Final PEIS/PEIR).

SUMMARY: Pursuant to the National Environmental Policy Act and the California Environmental Quality Act, the Bureau of Reclamation (Reclamation) and the Colusa Basin Drainage District (District) have prepared a joint Final PEIS/PEIR for the Integrated Resources Management Program for Flood Control in the Colusa Basin (Program). The Program is comprised of three elements: Construction of a series of flood detention dams and basins on selected ephemeral streams that cause flooding in the Basin; implementation of several upland, riparian, and wetland environmental restoration measures that will help reduce soil erosion and sedimentation and restore degraded habitat; and development of a water supply that could be used for environmental purposes. The Final PEIS/PEIR describes and presents the potential environmental effects of the three Program elements. Notice of the Draft Programmatic Environmental Impact Statement/Draft Environmental Impact Report (DEIS/DEIR) was published in the **Federal Register** on June 2, 2000 (65 FR 35392). The public hearing was held on August 9, 2000. The written comment period ended August 25, 2000. The Final PEIS/PEIR contains responses to all comments received and changes made to the text of the DEIS/DEIR as a result of those comments.

DATES: Reclamation will not make a decision on the proposed action until 30 days after release of the Final PEIS/PEIR. After the 30-day waiting period, Reclamation will complete a Record of Decision (ROD). The ROD will state the action that will be implemented and will discuss all factors leading to the decision.

ADDRESSES: Copies of the Final PEIS/PEIR may be requested from Ms. Gaye Lopez, Colusa Basin Drainage District, at 530–795–3038, or Mr. Russ Smith, Reclamation, at 530–275–1554.

See Supplementary Information section for locations where copies of the Final PEIS/PEIR are available for public inspection.

FOR FURTHER INFORMATION CONTACT: Ms. Gaye Lopez, Colusa Basin Drainage District, at 530–795–3038, or Mr. Russ Smith, Reclamation, at 530–275–1554.

SUPPLEMENTARY INFORMATION: The Program encompasses an area of about 1,036,000 acres within the Basin, extending from Orland in the north to Knights Landing in the south, and includes lands in Glenn, Colusa, and Yolo Counties. The Sacramento River and Coastal Range foothills form its eastern and western boundaries, respectively. Within this area, the District encompasses about 650,000 acres.

The proposed action is to construct flood detention dams and basins on certain ephemeral streams in the foothills west of the Basin that cause the greatest flood damage. Reclamation and the District also propose to implement approximately 10,000 acres of environmental restoration measures to help restore degraded upland, riparian, and wetland habitats in the project area. In addition, the detention basins could provide a water supply that could be used for environmental purposes.

The goal of the Program is to substantially reduce flood damages and restore upland, riparian, and wetland habitats that have been historically degraded in the Colusa Basin. In addition to a No Program Alternative, which involves the continued use of the existing Colusa Basin Drain for drainage management and inadequate flood flow conveyance, six program alternatives are examined. Alternatives la, 2a, and 3a include the proposed construction of 14, 8, and 5 foothill flood detention dams and reservoirs, respectively, and about 10,000 acres of upland, riparian, and wetland restoration measures in the Colusa Basin. Alternatives lb, 2b, and 3b include all the elements of Alternatives la, 2a, and 3a, respectively, and would also be operated to provide a water supply that could be used for environmental purposes, including the dedication of some reservoir space for water storage.

Copies of the Final PEIS/PEIR are available for public inspection at the following locations:

- Bureau of Reclamation, Denver Office Library, Building 67, Room 167, Denver Federal Center, 6 and Kipling, Denver CO 80225; telephone: 303–445–2064
- Bureau of Reclamation, Office of Public Affairs, 2800 Cottage Way, Sacramento CA 95825–1898; telephone: 916–978–5100
- Natural Resources Library, U.S. Department of the Interior, 1849 C Street NW, Main Interior Building, Washington DC 20240–0001
- Sacramento State University Library, 6000 J Street, Sacramento CA 95521
- Princeton Public Library, P.O. Box 97, Princeton CA 95970–0097
- Elk Creek Library, Box 163, Elk Creek CA 95939–0163
- Bayliss Library, Rd 39 and West Bayliss, Bayliss CA 95943
- Willows City Library, 201 N. Lassen Street, Willows CA 95988
- Yolo County Library, 373 N. College, Woodland CA 95695
- Grimes Library, P.O. Box 275, Grimes CA 95950
- Orland City Library, 333 Mill Street, Orland CA 95963
- Shasta College Library, 1065 Old Oregon Trail, Redding, CA 96099
- Arbuckle Library, 7th & King, Arbuckle, CA 95912
- Butte Community College Library, 3536 Butte Campus Drive, Oroville, CA 95965
- Campus Library, Humboldt State University, Arcata, CA 95521
- Esparto Branch Library, 17155 Yolo Avenue, Esparto, CA 95627
- Willows Public Library, 201 North Lassen Street, Willows, CA 94988
- Shields Library, University of California-Davis, Davis, CA 95616

Our practice is to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home address from public disclosure, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold a respondent's identity from public disclosure, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public disclosure in their entirety.

Dated: June 29, 2001.

Lowell F. Ploss,

Deputy Regional Director.

[FR Doc. 01–18044 Filed 7–18–01; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Renewal of Sacramento River Settlement Contracts, Central Valley Project, CA

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of intent to prepare an environmental document (environmental assessment or environmental impact statement) and notice of public meetings.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), the Bureau of Reclamation (Reclamation) proposes to prepare an environmental document to evaluate alternatives for renewal of long-term contracts with the entities and individuals asserting rights to divert water from the natural flow of the Sacramento River. These entities and individuals, known as the Sacramento River settlement contractors, typically receive both non-Central Valley Project water, referred to as base supply, and supplemental water from the Central Valley Project, referred to as Project water. The current contracts expire in 2004, and the proposed renewals would extend for at least 25 years.

At present it is not clear whether the scope of the action and anticipated project impacts will require preparation of an environmental impact statement (EIS) instead of an environmental assessment (EA). However, to ensure the timely and appropriate level of NEPA compliance and to limit potential future delays to the project schedule, Reclamation is proceeding as if the project impacts would require preparation of an EA. Reclamation will re-evaluate the need for an EIS after obtaining written and oral comments on the project scope, alternatives and environmental impacts, and after Reclamation's evaluation of potential impacts of the proposed project. Reclamation will publish a notice of change if a decision is made to prepare an EIS rather than an EA. However, the scoping process to be conducted will suffice for either course of action.

There are no known Indian Trust Asset or environmental justice issues associated with the proposed action.

DATES: Three scoping meetings will be held to solicit comments from interested parties to assist in determining the scope of the environmental analysis and to identify the significant issues related to this proposed action. The meeting dates are:

- Monday, August 6, 2001, 1 to 4 p.m., Tracy, California
- Tuesday, August 7, 2001, 1 to 4 p.m., Concord, California
- Wednesday, August 8, 2001, 1 to 4 p.m., Red Bluff, California

Written comments on the scope of the environmental document should be mailed to Reclamation at the address below by August 27, 2001.

ADDRESSES: The meeting locations are as follows:

- Tracy at Veterans of Foreign Wars, 430 West Grant Line Road
- Concord at Hilton Hotel, 1970 Diamond Boulevard

- Red Bluff at Red Bluff Community/ Senior Center, 1500 South Jackson Street

Written comments on the scope of the environmental document should be sent to Buford Holt, Environmental Specialist, Bureau of Reclamation, Northern California Area Office, 16349 Shasta Dam Boulevard, Shasta Lake, CA 96019.

FOR FURTHER INFORMATION CONTACT: Buford Holt at the above address, by telephone at (530) 275–1554, or e-mail at bholt@mp.usbr.gov.

SUPPLEMENTARY INFORMATION: The Central Valley Project (CVP) was first authorized as a Federal project in 1935 and includes facilities on the Trinity River, Sacramento River, American River, Sacramento-San Joaquin Delta, San Joaquin River, Stanislaus River and offstream storage and conveyance facilities associated with the San Luis Reservoir and Delta Mendota Canal. Construction of dams on the Sacramento River and the Trinity River substantially modified the flows of the Sacramento River. Prior to construction of the CVP, individuals and entities along the Sacramento River were diverting water for irrigation and municipal and industrial uses under various claims of right. In order to settle the controversy over assertions of water rights, the United States, acting through the Bureau of Reclamation, negotiated contracts that provided for agreement on diversion of water and CVP water service. The term of these Sacramento River settlement contracts was not to exceed 40 years and the contracts expire on March 31, 2004. The settlement contracts provide for renewal which must be accomplished prior to March 31, 2004.

Our practice is to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home address from public disclosure, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold a respondent's identity from public disclosure, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public disclosure in their entirety.

Special Services

Persons requiring any special services should contact Sammie Cervantes at (916) 978–5104. Please notify Ms. Cervantes as far in advance of the particular meeting as possible, but no later than 3 working days prior to the meeting to enable Reclamation to secure the services. If a request cannot be honored, the requester will be notified.

Dated: June 29, 2001.

Laura Allen,

Deputy Regional Environmental Officer.

[FR Doc. 01–18043 Filed 7–18–01; 8:45 am]

BILLING CODE 4310–MN–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–459]

Certain Garage Door Operators Including Components Thereof; Notice of Investigation

AGENCY: International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 15, 2001, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of The Chamberlain Group, Inc. of Elmhurst, Illinois. Supplements to the complaint were filed on June 21 and July 9, 2001. The complaint, as supplemented, alleges violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain garage door operators including components thereof by reason of infringement of claims 1–8 of U.S. Letters Patent Re. 35,364 and claims 5–30 of U.S. Letters Patent Re. 36,703. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and permanent cease and desist orders.

ADDRESSES: The complaint and supplements, except for any confidential information contained therein, are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's ADD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server at http://www.usitc.gov. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS–ON–LINE) at *http://dockets.usitc.gov/eol/public*.

FOR FURTHER INFORMATION CONTACT: David O. Lloyd, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202–205–2576.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2001).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on July 13, 2001, *Ordered That*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain garage door operators including components thereof by reason of infringement of claims 1–8 of U.S. Letters Patent Re. 35,364 or claims 5–30 of U.S. Letters Patent Re. 36,703 and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—The Chamberlain Group, Inc., 845 Larch Avenue, Elmhurst, Illinois 60126–1196.

(b) The respondents are the following companies alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Linear Corporation, 2055 Corte Del Nogal, Carlsbad, California 92009–1498

Napoleon Spring Works, Inc., 111 Weires Drive, Archbold, Ohio 43502

Lynx Industries, Inc., 111 Weires Drive, Archbold, Ohio 43502

Innovative Home Products, Inc., 2400 East Lincoln Street, Birmingham, Michigan 48009–7126

Wayne-Dalton Corporation, One Door Drive, P.O. Box 67, Mt. Hope, Ohio 44660

Guardian Access Corporation, No. 1, Pei Yuan 2. Rd., Chung Li City, Taiwan

(c) David O. Lloyd, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Room 401, Washington, DC 20436, who shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, the Honorable Sidney Harris is designated as the presiding administrative law judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d) and 210.13(a), such responses will be considered by the Commission if received no later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and to authorize the administrative law judge and the Commission, without further notice to that respondent, to find the facts to be as alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings, and may result in the issuance of a limited exclusion order or a cease and desist order or both directed against that respondent.

Issued: July 16, 2001.

By Order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–18126 Filed 7–18–01; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–448]

Certain Oscillating Sprinklers, Sprinkler Components, and Nozzles; Notice of Commission Determination Not To Review an Initial Determination Adding a Respondent to the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (ID) of the presiding administrative law judge (''ALJ'') in the above-captioned investigation adding Dayco Products Inc. (''Dayco'') as a respondent to the investigation.

FOR FURTHER INFORMATION CONTACT: Laurent de Winter, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202–708–5452. General information concerning the Commission may also be obtained by accessing its Internet server (http://www.usitc.gov). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS-ON-Line) at http://dockets.usitc.gov/eol.public. Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation, which concerns allegations of unfair acts in violation of section 337 of the Tariff Act of 1930 in the importation and sale of certain oscillating sprinklers, sprinkler components, and nozzles, on February 9, 2001 66 FR 9721. On June 4, 2001, complainant L.R. Nelson Corporation moved, pursuant to Commission rule 210.14(b), to amend the complaint and notice of investigation to add Dayco Products, Inc. (''Dayco'') as a respondent in this investigation with respect to infringement of U.S. Letters Patent 6,036,117.

On June 14, 2001, the presiding administrative law judge (ALJ) (Judge Luckern) issued an ID (Order No. 9) (copy attached) adding Dayco as a respondent to the investigation. No petitions for review of the ID were filed.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and Commission rule 210.42 (19 CFR 210.42).

Copies of the nonconfidential version of the ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202–205–2000.

By order of the Commission.

Issued: July 16, 2001.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–18125 Filed 7–18–01; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–444]

Certain Semiconductor Light Emitting Devices, Components Thereof, and Products Containing Same; Notice of a Commission Determination Not To Review an Initial Determination Terminating the Investigation Based on Withdrawal of the Complaint

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ's'') initial determination (''ID'') granting a motion to terminate the above-captioned investigation based on withdrawal of the complaint.

FOR FURTHER INFORMATION: Timothy P. Monaghan, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone (202) 205–3152.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on January 9, 2001, based on a complaint by Rohm Co. Ltd. (''Rohm'') alleging that respondents Nichia Corporation and Nichia American Corporation (''Nichia'') violated section 337 of the Tariff Act of 1930 by importing, selling for importation, or selling within the United States after importation certain semiconductor light emitting devices, components thereof, and products containing same that infringe certain claims of U.S. Letters Patent Nos. 6,084,899 and 6,115,399.

On April 27, 2001, complainant Rohm filed a motion pursuant to rule 210.21(a) to terminate the investigation on the basis of withdrawal of the complaint. On May 9, 2001, the Nichia respondents

filed a response to Rohm's motion to terminate the investigation. Nichia did not oppose the motion to terminate, but requested that the ALJ terminate the investigation ''with prejudice'' in view of a Nichia's motion for sanctions against Rohm for abuse of Commission process. The Commission investigative attorney supported Rohm's motion to terminate the investigation.

On June 27, 2001, the presiding ALJ issued an ID granting Rohm's motion to terminate the investigation, but denying Nichia's request to terminate the investigation ''with prejudice.''

None of the parties filed a petition to review the subject ID. The Commission subsequently determined not to review the subject ID.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and Commission rule 210.42, 19 CFR 210.42. Copies of the subject ID and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202–205–2000. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http:/www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS–ON–LINE) at *http://dockets.usitc.gov/eol/public.*

Issued: July 16, 2001.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–18100 Filed 7–18–01; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Clean Air Act (''CAA'')

Consistent with the policy set forth in the Department of Justice regulations at 28 CFR 50.7, notice is hereby given that on July 12, 2001, a proposed Consent Decree was lodged with the United States District Court for the Southern District of Illinois, in *United States and State of Illinois* v. *Clark Refining and Marketing, Inc.,* Civil Action No. 99–87 (GPM). The proposed Consent Decree settles claims asserted by the United States on behalf of the U.S. Environmental Protection Agency, and the State of Illinois, pursuant to section 113(b) of the Clean Air Act, 42 U.S.C. 9613(b), and the federally enforceable State Implementation Plan (''SIP''), in connection with operation of the Clark Refining (now The Premcor Refining Group Inc.) petroleum refinery in Hartford, Illinois.

The Consent Decree requires Premcor to pay $2 million in civil penalties for alleged violation of the Prevention of Significant Deterioration requirements in Part C of the CAA and the implementing regulations at 40 CFR 52.21, as well as violations of SIP emission limits at the refinery's fluid catalytic cracking unit (''FCCU''). The proposed Decree also requires Premcor to install a wet gas scrubber on its FCCU, to control emissions of sulfur dioxide and particulate matter. Additional pollution control measures in the decree include a program that will result in installation of low-NO_X or ultra low-NO_X burners at selected heaters and boilers at the Hartford refinery.

The Department of Justice will receive written comments relating to the proposed consent Decree for thirty (30) days from the date of publication of this notice. Comments should be directed to the Acting Assistant Attorney General, Environment and Natural Resources Division, U.S. Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Clark Refining and Marketing, Inc.,* DOJ Reference # 90–5–2–1–2032.

The proposed Consent Decree may be examined at the Office of the United States Attorney for the Southern District of Illinois, 9 Executive Drive, Suite 300, Fairview Heights, Illinois 62208 (contact William E. Coonan, (618) 628–3700), and at the offices of the U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604–3590 (contact Brian Barwick, (312) 886–6620. Copies may also be obtained by mail from the Department of Justice Consent Decree Library, PO Box 7611, Washington, DC 20044–7611. In requesting copies, please refer to the case name and DOJ reference number an enclose a check in the amount of $9.00 (25 cents per page reproduction cost) payable to the Consent Decree Library.

William D. Brighton,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 01–18079 Filed 7–18–01; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Clean Water Act

In accordance with 28 CFR 50.7, 38 FR 19029, notice is hereby given that on June 28, 2001, a Consent Decree was lodged with the United States District Court for the District of Massachusetts in *United States* v. *National Railroad Passenger Corporation* Civil Action No. 01–11121–RWZ. A complaint in the action was also filed simultaneously with the lodging of the Consent Decree. In the complaint the United States, on behalf of the U.S. Environmental Protection Agency (EPA), alleges that the defendant National Railroad Passenger Corporation (Amtrak) violated the Clean Water Act, 33 U.S.C. 1251, *et seq.*, at nine Amtrak facilities in Massachusetts, Connecticut and Rhode Island. The violations involve EPA requirements for control of storm water discharges; requirements of Amtrak's pollutant discharge permits; pretreatment requirements; Spill Prevention Control and Countermeasure requirements; and a small oil spill into navigable waters. The consent decree requires Amtrak to pay a cash penalty of $500,000, and implement two Supplemental Environmental Projects at a cost of $900,000. The consent decree also requires Amtrak to comply with relevant environmental laws at the nine identified facilities, and to also conduct a multi-media compliance audit for each of its 51 facilities nation-wide. Amtrak is also required to implement a comprehensive Environmental Management System involving the entire company.

The Department of Justice will receive comments relating to the proposed Consent Decree for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, Department of Justice, P.O. Box 7611, Washington, DC 20044, and should refer to *United States* v. *National Railroad Passenger Corporation*, D.J. Ref. 90–5–1–1–06798.

The proposed consent decree may be examined at the office of the United States Attorney, Suite 9200, 1 Courthouse Way, Boston, Massachusetts 02110, and at the Region I office of the Environmental Protection Agency, One Congress Street, Suite 1100, Boston, Massachusetts 02114. A copy of the proposed consent decree may also be obtained by mail from the Department of Justice Consent Decree Library, PO Box 7611, Washington, DC 20044. In requesting a copy, please enclose a

check (there is a 25 cent per page reproduction cost) in the amount of $37.75 payable to the ''Consent Decree Library.''

Ronald G. Gluck,

Assistant Chief, Environmental Enforcement Section, Environment & Natural Resources Division.

[FR Doc. 01–18078 Filed 7–18–01; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

Notice is hereby given that on July 11, 2001, the United States lodged a proposed Second Amendment to the Consent Decree with the United States District Court for the Northern District of Illinois, Western Division, in *United States, et al.* v. *City of Rockford, Illinois,* Civil No. 98C50026 (N.D. Ill.), under the Comprehensive Environmental Response, Compensation and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9601 *et seq.* The proposed Second Amendment to the Consent Decree modifies the Amended Consent Decree entered by the United States District Court for the Northern District of Illinois on or about January 13, 1999, which resolved certain claims of the United States and the State of Illinois against the City of Rockford, Illinois, under sections 106(a) and 107(a) of CERCLA, 42 U.S.C. 9606(a) and 9607(a), pertaining to the Southeast Rockford Groundwater Contamination (the ''Site'') located in Rockford, Winnebago County, Illinois, In that Amended Consent Decree, the City of Rockford reaffirmed the terms and conditions of the original Consent Decree entered by the Court on or about April 9, 1998, to perform the remedial action selected by U.S. EPA in its September 30, 1995, Record of Decision and to reimburse certain costs incurred by Plaintiffs at the Site. The Amended Consent Decree resolved additional claims of the Plaintiffs against the City of Rockford, and resolved potential claims of the Plaintiffs against certain Covenant Beneficiaries. As specified in the Amended Consent Decree, the City of Rockford and Covenant Beneficiaries received covenants not to sue and contribution protection.

The Second Amendment to the Consent Decree adds 11 parties who will participate in the settlement by paying an aggregate sum of $142,001.59 to the City of Rockford to be paid to the Plaintiffs, to reimburse certain costs incurred by the Plaintiffs at the Site, and by executing and transmitting Covenant Beneficiary Forms. The settlement resolves potential claims of the Plaintiffs against these added Covenant Beneficiaries, who will receive the covenants not to sue and contribution protection provided to such parties in the Amended Consent Decree. All other provisions of the Amended Consent Decree and original Consent Decree not modified by the Second Amendment to the consent Decree remain in full force and effect.

The Department of Justice also provides notice that under section 7003(d) of the Resource Conservation and Recovery Act (''RCRA''), 42 U.S.C. 6973(d), the public may request an opportunity for a public meeting at which time they may offer comment. The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed Second Amendment to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, United States Department of Justice, Washington, DC 20530, and should refer to *United States et al.* v. *City of Rockford, Illinois,* Civil No. 98C50026 (N.D. Ill.), and DOJ Reference No. 90–11–3–945.

The proposed consent decree may be examined at: (1) The Office of the United States Attorney for the Northern District of Illinois, Western Division, 308 West State St., Suite 300, Rockford, Illinois 61101 (815–987–4444); and (2) the United States Environmental Protection Agency (Region 5), 77 West Jackson Boulevard, Chicago, Illinois 60604–3590 (contact: Thomas Turner (312) 886–6613). A copy of the proposed Second Amendment to the Consent Decree may be obtained by mail from the Consent Decree Library, U.S. Department of Justice, P.O. Box 7611, Washington, DC 20044–7611. In requesting a copy, please refer to the referenced case and DOJ Reference Number and enclose a check in the amount of $3.00 for the consent decree and one appendix only (12 pages at 25 cents per page reproduction costs), or $19.50 for the consent decree, appendix and 11 covenant beneficiary forms (78 pages), made payable to the Consent Decree Library.

William D. Brighton,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 01–18081 Filed 7–18–01; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with 28 CFR 50.7 and section 122 of the Comprehensive Environmental Response, Compensation and Liability Act (''CERCLA''), 42 U.S.C. 9622, the Department of Justice gives notice that a proposed consent decree, in *United States* v. *State of Wisconsin, et al.,* Civil No. 01–C–0394–S (W.D. Wisc.), was lodged with the United States District Court for the Western District of Wisconsin on July 10, 2001, pertaining to the Refuse Hideaway Landfill Superfund Site located in the Town of Middleton, Dane County, Wisconsin (the ''Site''). The proposed consent decree would resolve the United States' civil claims under sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607, against the Settling Defendants: The State of Wisconsin, 3 transporters and 157 generators, including 8 municipalities. The proposed consent decree also resolves claims against 4 Settling Federal Agencies.

Under the proposed consent decree, the State of Wisconsin, as Settling Performing Party, is obligated to finance and perform the completion of the remedial action at the Site and conduct long term operation and maintenance (''O&M'') at the Site, as specified in the U.S. Environmental Protection Agency's (''FPA's'') Record of Decision (''ROD''), issued June 28, 1995, as modified under an Explanation of Significant Differences (''ESD''), issued September 30, 1998, at an estimated net present value of $1.3 million. The remaining 160 Settling Defendants would be obligated to pay approximately $3.5 million to the United States and State of Wisconsin. The United States would receive $793,895 in reimbursement of past response costs and future response costs at the Site, and the State would receive the balance of the payments to be used for financing the State's future response work at the Site and for reimbursement of the State's past response costs incurred in connection with the Site. In addition, the United States, on behalf of the 4 Settling Federal Agencies, would pay $32,845 to the Superfund in reimbursement of past response costs and premium payments for future response costs incurred and to be incurred at the Site.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed

consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, United States Department of Justice, Washington, DC 20530, and should refer to *United States* v. *State of Wisconsin, et al.,* Civil No. 01–C–0394–S (W.D. Wisc.), and DOJ Reference No. 90–11–2–1184.

The proposed consent decree maybe examined at: (1) The Office of the United States Attorney for the Western District of Wisconsin, 660 West Washington Avenue, Suite 200, Madison, Wisconsin 53703, (608–264–5158); and (2) the United States Environmental Protection Agency (Region 5), 77 West Jackson Boulevard, Chicago, Illinois 60604–3590 (contact: Jacqueline Kline (312–886–7167)). A copy of the proposed consent decree may be obtained by mail from the Consent Decree Library, U.S. Department of Justice, PO Box 7611, Washington, DC 20044–7611. In requesting a copy, please refer to the referenced case and DOJ Reference Number and enclose a check in the amount of $18.00 for the consent decree only (72 pages, at 25 cents per page reproduction costs), or $110.50 for the consent decree and all appendices (442 pages), made payable to the Consent Decree Library.

William D. Brighton,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 01–18080 Filed 7–18–01; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Financial Services Technology Consortium, Inc.: Financial Agent Secure Transaction (FAST) Project

Notice is hereby given that, on June 28, 2000, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Financial Services Technology Consortium, Inc.: Financial Agent Secure Transaction (FAST) Project has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the identities of the parties are American Bankers Association, Washington, DC; BAI, Chicago, IL; Bank of America, Richmond, VA; Certicom Corp., Hayward, CA; Chase Manhattan Bank, Hicksville, NY; Citibank N.A., New York, NY; Experian, Orange, CA; Federal Reserve Bank of Boston, Boston, MA; First Union National Bank, Charlotte, NC; Hewlett-Packard Company, Cambridge, MA; Huntington National Bank, Columbus, OH; NACHA, Herndon, VA; National Center for Manufacturing Sciences, Inc., Ann Arbor, MI; National Institute of Standards and Technology, Gaithersburg, MD; Star Systems, Inc., Reston, VA; Unisys Corporation, Burlington, MA; and Wells Fargo Services & Company, Minneapolis, MN.

The nature and objectives of the venture are research and development activities concerning an economically viable architecture/framework/protocol for entities, unknown to each other and possessing no common authentication mechanism, to securely conduct transactions over the Internet by leveraging the relationship each has with its respective financial institution, electronic commerce and other on-line business and personal financial transactions.

Constance K. Robinson,

Director of Operations Antitrust Division.

[FR Doc. 01–18083 Filed 7–18–01; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—J Consortium, Inc.

Notice is hereby given that, on April 16, 2001, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), J Consortium, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Praxis Critical System, Bath, United Kingdom; IONA Technologies, Waltham, Ma; BoldFont, Davis, CA; Micro Design Online, San Jose, CA; Muhammad Amir (individual member), Sindh, Pakistan; Kutsal Baser (individual member), Bishkek, Kyrgyzstan; Burhan A. Sh. (individual member), Lahore, Pakistan; Olivier Chamley (individual member), Pessac, France; Eric Dorion (individual member), Val-Belair, Quebec, Canada; Johann Gruber (individual member), Vienna, Austria; Samantha Gunasena (individual member), Thudella, Jaela, West Provence, Sri Lanka; Jmchen, Hangzhou, Zhejiang, People's Republic of China; Ouma Konyino, Maseo, Kenya; Dip.Ing. Kurt Layer, Unterpremstaetten, Austria; Jukka Peltoa, Espoo, Finland; Gerd Loos (individual member), Hamburg, Germany; Sharath Gowd R, (individual member), Banglore, Karnataka, India; David Sawyer (individual member), Wolcott, CT; Deepak Shah, Bangalore, Karnataka, India; Swamynathan Sivasubramaniyan, Aurora, CO; Virkram M P, Bangalore, Karnataka, India; Wangzhi, Hangzhou, Zhejiang, People's Republic of China; Amir Wasim (individual member), Lahore, Pakistan; and Brian Leslie Williams (individual member), Singapore, Singapore have been added as parties to this venture. Also, EIBA, Brussels, Belgium has been dropped as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and J Consortium, Inc. intends to file additional written notification disclosing all changes in membership.

On August 9, 1999, J Consortium, Inc. filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 21, 2000 (65 FR 15175).

The last notification was filed with the Department on January 19, 2001. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on March 8, 2001 (66 FR 13970).

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 01–18084 Filed 7–18–01; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Management Service Providers Association, Inc.

Notice is hereby given that, on May 15, 2001, pursuant to section 6(a) of the

National Cooperative Research and Production Act of 1993, 15 U.S.C. *et seq.* (''The Act''), Management Services Providers Association, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, AimNet Solutions, Inc., Norwalk CT; Applicant, Seattle, WA; CoreFuzion, Inc., Santa Clara, CA; Eccord Systems Ltd., San Jose, CA; Hitachi Electronics Services Co., Ltd., Yokohama, Japan, hub information technology limited, Sydney, New South Wales, Australia; ISP Co., Ltd., Kangriam-ku, Seoul, Republic of Korea; IT Guardian, Kooloon, Hong Kong—China; Iworld Holdings Limited, Seoul, Republic of Korea; NetEffect Corporation, Atlanta, GA; Omegon, Inc., Somerset, NJ; Progress Software Corporation, Bedford, MA; RedSiren, Pittsburgh, PA; SaskTel—QuantumLynx, Regina, Saskatchewan, Canada; SPS Gensys, Reeusijk, Netherlands; and Totality Corporation, San Francisco, CA have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Management Services Providers Association, Inc. intends to file additional written notification disclosing all changes in membership.

On October 20, 2000, Management Services Providers Association, Inc. filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 24, 2000 (65 FR 70613).

The last notification was filed with the Department on February 5, 2001. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on March 8, 2001 (66 FR 13970).

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 01–18085 Filed 7–18–01; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Microcontaminant Reduction Venture

Notice is hereby given that, on June 13, 2001, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''Act''), the Microcontaminant Reduction Venture (''the Venture'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature an objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the identities of the parties are Vulcan Materials Company, Birmingham, AL; and KMG Bernuth, Inc., Houston, TX.

The nature and objectives of the venture are to develop cost effective methods for reduction of microcontaminants such as dioxins, furans, and hexachlorobenzene in the pentachlorophenol manufactured by the participants.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 01–18086 Filed 7–18–01; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—National Center for Manufacturing Sciences, Inc.

Notice is hereby given that, on December 20, 2000, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), the National Center for Manufacturing Sciences, Inc. (''NCMS'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Didactics, Inc., Alexandria, VA; Opticore, Inc., Troy, MI; and VE Technologies, Inc., Blacksburg, VA have been added as parties to this venture. Also CAMotion, Inc., Atlanta, GA; TRW Broadband Communication Network, Carson, CA; Alberta Research Council, Edmonton, Alberta, Canada; Independent Lubricant Manufacturers Association, Alexandria, VA; and State Board of Technical Colleges, St. Paul, MN have been dropped as parties to this venture. In addition, Advanced Manufacturing Sciences (IAMS) has changed its name to TechSolve, Inc., Ann Arbor, MI.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and NCMS intends to file additional written notification disclosing all changes in membership.

On February 20, 1987, NCMS filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 17, 1987 (52 FR 8375).

The last notification was filed with the Department on July 19, 2000. A notice has not yet been published in the **Federal Register**.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 01–18082 Filed 7–18–01; 8:45 am]

BILLING CODE 4410–11–M

NATIONAL COMMISSION ON LIBRARIES AND INFORMATION SCIENCE

Sunshine Act Meeting; Notice

AGENCY: U. S. National Commission on Libraries and Information Science

ACTION: Notice of meeting.

SUMMARY: The U.S. National Commission on Libraries and Information Science is holding an open business meeting to discuss administrative matters and NCLIS international projects.

DATE AND TIME: NCLIS Business Meeting—August 21, 2001, 3:30 p.m. to 5:30 p.m., Boston, Massachusetts.

ADDRESS: Meeting location—Boston Public Library, Mezzanine Conference Room (MCR), 700 Boylston Street, Copley Square, Boston, Massachusetts 02116.

STATUS: Open meeting.

FOR FURTHER INFORMATION CONTACT: Rosalie Vlach, Director, Legislative and Public Affairs, U.S. National Commission on Libraries and Information Science, 1110 Vermont

Avenue, NW., Suite 820, Washington, DC 20005, e-mail *rvlach@nclis.gov,* fax 202–606–9203 or telephone 202–606 9200.

SUPPLEMENTARY INFORMATION:

The Commission will discuss administrative matters and NCLIS international projects, including:

- International application of the results of the NCLIS study, A Comprehensive Assessment of Public Information Dissemination;
- Preparation for the International Leadership Conference on Information Literacy;
- NCLIS activities with the European Union;
- Transfer of the NCLIS Survey of U.S. Participation in International Organizations and Activities Which Address Major Library and Information Science Policy Issues to the School of Library Science, University of Pittsburgh; and
- Transfer of Sister Libraries: A White House Millennium Council Project to the United Nations Associated Libraries.

The meeting is open to the public, subject to space availability. To make special arrangements for physically challenged persons, contact Rosalie Vlach, Director, Legislative and Public Affairs, 1110 Vermont Avenue, NW., Suite 820, Washington, DC 20005, e-mail *rvlach@nclis.gov,* fax 202–606–9203 or telephone 202–606–9200.

Dated: July 11, 2001.

Judith C. Russell,

NCLIS Deputy Director.

[FR Doc. 01–18185 Filed 7–17–01; 2:13 pm]

BILLING CODE 7527–$$–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 01–089]

NASA Advisory Council, Minority Business Resource Advisory Committee Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announce a forthcoming meeting of the NASA Advisory Council, Minority Business Resource Advisory Committee.

DATES: Thursday, August 23, 2001, 9 a.m. to 4 p.m., and Friday, August 24, 2001, 9 a.m. to 12 noon.

ADDRESSES: NASA Headquarters, 300 E Street, SW., Room 9H40, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph C. Thomas III, Code K, National Aeronautics and Space Administration, Room 9K70, 300 E Street, SW., Washington, DC 20546–0001, (202) 358–2088.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Overview of NASA
—Welcoming of new MBRAC members
—Purpose of MBRAC Committee
—Travel Procedures
—Goals for MBRAC V
—Public Comment
—Overview of NASA's Small Business Program
—MBRAC's Impact on NASA
—Status of Open Committee Recommendations

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Dated: July 12, 2001.

Beth M. McCormick,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 01–18045 Filed 7–18–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 01–090]

U.S. Centennial of Flight Commission; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces the first meeting of the First Flight Centennial Federal Advisory Board. The Advisory Board will offer counsel to the U.S. Centennial of Flight Commission as the Commission develops support for activities involving the public in the celebration of the 100th anniversary of powered flight, December 17, 2003.

DATES: Thursday, August 9, 2001, 9 a.m. to 5 p.m.

ADDRESSES: National Aeronautics and Space Administration, 300 E Street, SW, Room 9H40 (PRC), Washington, DC 20546. Attendees must check in at the Security Desk to be cleared to the 9th floor conference room.

FOR FURTHER INFORMATION CONTACT: Ms. Beverly Farmarco, Code ZC, National Aeronautics and Space Administration, Washington, DC 20546, 202/358–1903.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Welcome
—Brief Remarks
—Introductions
—Legislative Intent/Content
—Role of the Advisory Board & Meeting Objectives
—Presentations by Major Centennial Organizations
—General Discussion
—Closing Remarks
—Adjourn

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Dated: July 13, 2001.

Beth M. McCormick,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 01–18046 Filed 7–18–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL COUNCIL ON DISABILITY

Advisory Committee Meeting/ Conference Call

AGENCY: National Council on Disability (NCD).

SUMMARY: This notice sets forth the schedule of the forthcoming meeting/ conference call for a working group of NCD's advisory committee—International Watch. Notice of this meeting is required under Section 10(a)(1)(2) of the Federal Advisory Committee Act (Pub. L. 92–463).

INTERNATIONAL WATCH: The purpose of NCD's International Watch is to share information on international disability issues and to advise NCD's Foreign Policy Team on developing policy proposals that will advocate for a foreign policy that is consistent with the values and goals of the Americans with Disabilities Act.

WORK GROUP: International Convention on the Human Rights of People with Disabilities.

DATE AND TIME: September 6, 2001, 12 p.m.–1 p.m. EDT

FOR INTERNATIONAL WATCH INFORMATION, CONTACT: Kathleen A. Blank, Attorney/ Program Specialist, NCD, 1331 F Street NW., Suite 1050, Washington, DC 20004; 202–272–2004 (Voice), 202–272–

2074 (TTY), 202–272–2022 (Fax), kblank@ncd.gov (e-mail).

AGENCY MISSION: NCD is an independent federal agency composed of 15 members appointed by the President of the United States and confirmed by the U.S. Senate. Its overall purpose is to promote policies, practices, and procedures that guarantee equal opportunity for all people with disabilities, regardless of the nature of the severity of the disability; and to empower people with disabilities to achieve economic self-sufficiency, independent living, and inclusion and integration into all aspects of society.

This committee is necessary to provide advice and recommendations to NCD on international disability issues.

We currently have balanced membership representing a variety of disabling conditions from across the United States.

OPEN MEETINGS/CONFERENCE CALLS: This advisory committee meeting/conference call of NCD will be open to the public. However, due to fiscal constraints and staff limitations, a limited number of additional lines will be available. Individuals can also participate in the conference call at the NCD office. Those interested in joining this conference call should contact the appropriate staff member listed above.

Records will be kept of all International Watch meetings/conference calls and will be available after the meeting for public inspection at NCD.

Signed in Washington, DC, on July 16, 2001.

Ethel D. Briggs,

Executive Director.

[FR Doc. 01–18059 Filed 7–18–01; 8:45 am]

BILLING CODE 6820–MA–M

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 25063; 812–12232]

Morgan Grenfell Investment Trust et al., Notice of Application

July 13, 2001.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 12(d)(1)(J) of the Investment Company Act of 1940 (''Act'') for an exemption from section 12(d)(1)(G)(i)(II) of the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit funds of funds relying on section 12(d)(1)(G) of the Act to invest in securities and other financial instruments.

APPLICANTS: Morgan Grenfell Investment Trust (''MG Trust''), BT Investment Portfolios (''BT Trust'') (collectively ''the Trusts''), Deutsche Asset Management, Inc. (''DeAM, Inc.'') and Deutsche Asset Management Investment Services Limited (''DeAMIS'') (together with DeAM, Inc., the ''Adviser'').

FILING DATES: The application was filed on August 21, 2000, and amended on June 29, 2001.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 7, 2001 and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Commission 450 Fifth Street, N.W., Washington, D.C. 20549–0609; Applicants, c/o Christopher P. Harvey, Esq. and Susan M. Tobin, Esq., Hale and Dorr LLP, 60 State Street, Boston MA 02109.

FOR FURTHER INFORMATION CONTACT: Lidian Pereira, Senior Counsel, at (202) 942–0524 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 450 Fifth Street, NW., Washington, DC 20549–0102 (telephone (202) 942–8090).

Applicant's Representation

1. The MG Trust is registered under the Act as an open-end management investment company and is organized as a Delaware business trust. The MG Trust consists of fifteen investment portfolios, including Emerging Markets Debt Fund (''Emerging Markets Debt''), Global Fixed Income Fund (''Global Fixed Income''), High Yield Bond Fund (''High Yield Bond'') and Total Return Bond Fund (''Total Return Bond''). The BT Trust is registered under the Act as an open-end management investment company and is organized as a New York trust. The BT Trust is part of a master-feeder structure in which BT Trust is the master portfolio and certain series of BT Investment Funds, an open-management investment company registered under the Act, among others, are feeders in a corresponding portfolio of BT Trust. The BT Trust consists of ten investment portfolio, including PreservationPlus Income Portfolio (''PreservationPlus'').

2. DeAM, Inc. and DeAMIS are each registered as an investment adviser under the Investment Advisers Act of 1940, and are under the common control of Deutsche Bank AG. DeAM, Inc. serves as investment adviser for High Yield Bond, Total Return Markets Debt and Global Fixed Income. Applicants request that the relief also apply to any existing or future registered open-end management investment company or series thereof advised by DeAM, Inc., De AMIS or any entity controlling, controlled by, or under common control with DeAM, Inc. or DeAMIS (together with Global Fixed Income, Total Return Bond and PreservationPlus, the ''Upper Tier Funds'') that wishes to invest in a registered open-management investment company or series thereof that is advised by DeAM, Inc., DeAMIS or any entity controlling, controlled by or under common control with DeAM, Inc. and DeAMIS and is part of the same ''group of investment companies'' (as defined in section 12(d)(1(G)(ii) of the Act) as the investing Upper Tier Fund (together with High Yield Bond and Emerging Markets Debt, the ''Underlying Funds'').[1]

3. Total Return Bond is a series of the Trust that seeks total return. To achieve this objective, Total Return Bond proposes to invest in shares of High Yield Bond and Emerging Markets Debt while also investing in other securities and financial instruments, including fixed income securities, futures, options, forward currency transactions and other derivative investments (''Other Securities'').[2] Similarly, Global Fixed Income seeks total return and proposes to invest in shares of High Yield Bond and Emerging Markets Debt while also investing in Other Securities. PreservationPlus seeks a high level of current income while seeking to maintain a stable value per share.

[1] All existing entities that currently intend to rely on the order are named as applicants. Any Upper Tier fund and any Underlying Fund that may rely on this order in the future will do so only in accordance with the terms and conditions of the application.

[2] These investments will not include shares of any registered investments companies that are not in the same group of investment companies as the Upper Tier Funds.

PreservationPlus proposes to invest in shares of High Yield Bond while also investing in Other Securities. High Yield Bond seeks high current income and, as a secondary objective, capital appreciation by investing primarily in U.S. dollar-denominated high yield bonds of U.S. and foreign issuers. Emerging Markets Debt seeks total return by investing primarily in high yield bonds of issuers in countries with new or emerging securities markets.

4. Applicants state that in the event an Underlying Fund is organized in a master-feeder structure, the Upper Tier Fund would not invest in shares of the feeder fund, but in interests of the master portfolio. In all such cases, the master portfolio would be part of the same group of investment companies (as defined in Section 12(d)(1)(G)(ii) of the Act) as the Upper Tier Fund. Such master portfolio is included in the term Underlying Fund.

Applicant's Legal Analysis

1. Section 12(d)(1)(A) of the Act provides that no registered investment company (''acquiring company'') may acquire securities of another investment company (''acquired company'') if such securities represent more than 3% of the acquired company's outstanding voting stock or more than 5% of the acquiring company's total assets, or if such securities, together with the securities of other investment companies, represent more than 10% of the acquiring company's total assets. Section 12(d)(1)(B) of the Act provides that no registered open end-investment company may sell its securities to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or cause more than 10% of the acquired company's voting stock to be owned by investment companies.

2. Section 12(d)(1)(G) of the Act provides that section 12(d)(1) will not apply to securities of an acquired company purchased by an acquiring company if: (i) The acquiring company and the acquired company are part of the same group of investment companies; (ii) the acquiring company holds only securities of acquired companies that are part of the same group of investment companies, government securities, and short-term paper; (iii) the aggregate sales loads and distribution-related fees of the acquiring company and the acquired company are not excessive under rules adopted pursuant to section 22(b) or section 22(c) of the Act by a securities association registered under section 15A of the Securities Exchange Act of 1934 or by the Commission; and (iv) the acquired company has a policy that prohibits it from acquiring securities of registered open-end management investment companies or registered unit investment trusts in reliance on section 12(d)(1)(F)(G). Applicants state that the proposed arrangement would comply with the provisions of section 12(d)(1)(G), but for the fact that an Upper Tier Fund's investments will include shares of one or more Underlying Funds as well as Other Securities.

3. Section 12(d)(1)(J) of the Act provides that the Commission may exempt persons or transactions from any provision of section 12(d)(1) if, and to the extent that, the exemption is consistent with the public interest and the protection of investors. Applicants requests an order under section 12(d)(1)(J) exempting them from section 12(d)(1)(G)(i)(II). Applicants assert that permitting Total Return Bond and other Upper Tier Funds to invest in the Underlying Funds and Other Securities as described in the application would not raise any of the concerns that the requirements of section 12(d)(1)(G) were designed to address.

Applicants' Conditions

Applicants agree that the order granting the requested relief will be subject to the following conditions:

1. Before approving any advisory contract under section 15 of the Act, the board of trustees of each of the MG Trust (on behalf of Total Return Bond and Global Fixed Income) and the BT Trust (on behalf of PreservationPlus) or other Upper Tier Fund, including a majority of the trustees who are not ''interested persons'' as defined in section 2(a)(19) of the Act, will find that advisory fees, if any, charged under the contract are based on services provided that are in addition to, rather than duplicative of, services provided pursuant to any Underlying Fund's advisory contract. Such finding, and the basis upon which it was made, will be recorded fully in the minute books of Total Return Bond, Global Fixed Income, PreservationPlus or other Upper Tier Fund.

2. Applicants will comply with all provisions of section 12(d)(1)(G), except for section 12(d)(1)(G)(i)(II) to the extent that it restricts Global Fixed Income, Total Return Bond, PreservationPlus or other Upper Tier Fund from investing in Other Securities as described in this application.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–18003 Filed 7–18–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44552; File No. S7–24–89]

Joint Industry Plan; Solicitation of Comments and Order Approving Request To Extend Temporary Effectiveness of Reporting Plan for Nasdaq/National Market Securities Traded on an Exchange on an Unlisted or Listed Basis, Submitted by the National Association of Securities Dealers, Inc., the Pacific Exchange, Inc. and the Boston, Chicago, Philadelphia, and Cincinnati Stock, Exchanges

July 13, 2001.

I. Introduction

On July 11, 2001, the Cincinnati Stock Exchange, Inc. (''CSE'') on behalf of itself and the National Association of Securities Dealers, Inc. (''NASD''), the Boston Stock Exchange, Inc. (''BSE''), the Chicago Stock Exchange, Inc. (''CHX''), Pacific Exchange, Inc. (''PCX''), and the Philadelphia Stock Exchange, Inc. (''Phlx'') (hereinafter referred to as the ''Participants'') [1] submitted to the Securities and Exchange Commission (''Commission'' or ''SEC'') a proposal to extend the operation of the Plan[2] for Nasdaq/National Market (''Nasdaq/NM'') securities traded on an exchange on an unlisted or listed basis.[3] The July 2001

[1] The CSE was elected as chair of the Operating Committee for the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Exchange-Listed Nasdaq/National Market System Securities and for Nasdaq/National Market System Securities Traded on Exchanges on an Unlisted Trading Privileges Basis (''Plan'') by the Participants.

[2] *See* letter from Jeffrey T. Brown, Vice President Regulation and General Counsel, CSE, to Jonathan G. Katz, Secretary, Commission, dated July 11, 2001 (''July 2001 Extension Request''). The signatories to the Plan are the Participants for purposes of this release; however, the BSE joined the Plan as a ''limited participant'' and reports quotation information and transaction reports only in Nasdaq/National Market securities listed on the BSE. Originally, the American Stock Exchange Inc. (''Amex'') was a Participant but withdrew its participation form the Plan in August 1994.

[3] Section 12 of the Securities Exchange Act of 1934 (''Act'') generally requires an exchange to trade only those securities that the exchange lists, except that Section 12(f) of the Act permits unlisted trading privileges (''UTP'') under certain circumstances. For example, Section 12(f) of the

Extension Request would extend the effectiveness of the Plan through August 20, 2001 and also would extend certain exemptive relief as described below. The July 2001 Extension Request does not seek permanent approval of the Plan because the Participants currently are negotiating certain amendments to the Plan for which they will seek approval in the future.[4]

II. Background

The Plan governs the collection, consolidation, and dissemination of quotation and transaction information for Nasdaq/NM securities listed on an exchange or traded on an exchange pursuant to a grant of UTP.[5] The Commission originally approved the Plan on a pilot basis on June 26, 1990.[6] The parties did not begin trading until July 12, 1993, accordingly, the pilot period commenced on July 12, 1993. The Plan has since been in operation on an extended pilot basis.[7]

III. Description of the Plan

The Plan provides for the collection from Plan Participants, and the consolidation and dissemination to vendors, subscribers and others, of quotation and transaction information in ''eligible securities.''[8] The Plan contains various provisions concerning its operation, including: Implementation of the Plan; Manner of Collecting, Processing, Sequencing, Making Available and Disseminating Last Sale Information; Reporting Requirements (including hours of operation); Standards and Methods of ensuring Promptness, Accuracy and Completeness of Transaction Reports; terms and Conditions of Access; Description of Operation of Facility Contemplated by the Plan; Method and Frequency of Processor Evaluation; Written Understandings of Agreements Relating to Interpretation of, or Participation in, the Plan; Calculation of the Best Bid and Offer (''BBO''); Dispute Resolution; and Method of Determination and Imposition, and Amount of Fees and Charges.[9]

IV. Exemptive Relief

In conjunction with the Plan, on a temporary basis, the Commission granted an exemption to vendors from Rule 11Ac1–2[10] under the Act regarding the calculation of the BBO[11] and granted the BSE an exemption from the provision of Rule 11Aa3–1[12] under the Act that requires transaction reporting plans to include market identifiers for transaction reports and last sale data. In the July 2001 Extension Request, the Participants ask that the Commission grant an extension of the exemptive relief described above to vendors until the BBO calculation issue is fully resolved. In addition, in the July 2001 Extension Request, the participants request that the Commission grant an extension of the exemptive relief described above to the BSE until August 20, 2001.

V. Solicitation of Comment

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether it is consistent with the Act. The Commission continues to solicit comment regarding the BBO calculation, the trade-through rule and any issues presented by changes occurring in the market place. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposal that are filed with the Commission, and all written communications relating to the proposal 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 at the Commission's Public Reference Room. All submissions should refer to File No. S7–24–89 and should be submitted by August 9, 2001.

VI. Discussion

The Commission finds that an extension of temporary approval of the operation of the Plan, as amended, through August 20, 2001, is appropriate and in furtherance of Section 11A[13] of the Act.[14] The Commission had previously stated that a revised Plan must be filed with the Commission by July 19, 2001, or the Commission will amend the Plan directly.[15] The

Act, among other things, permits exchanges to trade certain securities that are traded over-the-counter (''OTC/UTP''), but only pursuant to a Commission order or rule. The present order fulfills this Section 12(f) requirement. For a more complete discussion of the Section 12(f) requirement, *see* November 1995 Extension Order, *infra* note 7.

[4] In accordance with the Commission's statements in its order approving the establishment of the Nasdaq Order Display Facility and Order Collector Facility (''SuperMontage''), the Participants represent that they are revising the Plan. *See* Securities Exchange Act Release No. 438653 (January 19, 2001) 66 FR 8020 (January 26, 2001). Further in the July 2001 Extension Request, the Participants represented that a 12th amendment to the Plan (''Interim Plan'') has been unanimously approved by all Participants. However, due to scheduling limitations of certain Participants' Board meetings, the proposed Interim Plan could not be submitted to the Commission prior to the July 19, 2001 deadline. The Participants represent that they will endeavor to submit the Interim Plan by July 19, 2001.

[5] *See* Section 12(f)(2) of the Act, 15 U.S.C. 781(f)(2).

[6] *See* Securities Exchange Act Release No. 28146, 55 FR 27917 (July 6, 1990) (''1990 Plan Approval Order'').

[7] *See* Securities Exchange Act Release Nos. 34371 (July 13, 1994), 59 FR 37103 (July 20, 1994); 35221 (January 11, 1995)), 60 FR 3886 (January 19, 1995); 36102 (August 14, 1995), 60 FR 43626 (August 22, 1995); 36226 (September 13, 1995), 60 FR 49029 (September 21, 1995); 36368 (October 13, 1995), 60 FR 54091 (October 19, 1995); 36481 (November 13, 1995), 60 FR 58119 (November 24, 1995) (''November 1995 Extension Order''); 36589 (December 13, 1995), 60 FR 65696 (December 20, 1995); 36650 (December 28, 1995), 61 FR 358 (January 4, 1996); 36934 (March 6, 1996), 61 FR 10408 (March 13, 1996); 36985 (March 18, 1996), 61 FR 12122 (March 25, 1996); 37689 (September 16, 1996), 61 FR 50058 (September 24, 1996); 37772 (October 1, 1996), 61 FR 52980 (October 9, 1996); 38457 (March 31, 1997), 62 FR 16880 (April 8, 1997); 38794 (June 30, 1997) 62 FR 36586 (July 8, 1997); 39505 (December 31, 1997) 63 FR 1515 (January 9, 1998); 40151 (July 1, 1998) 63 FR 36979 (July 8, 1998); 40896 (December 31, 1998), 64 FR 1834 (January 12, 1999); 41392 (May 12, 1999), 64 FR 27839 (May 21, 1999) (''May 1999 Approval Order''); 42268 (December 23, 1999), 65 FR 1202 (January 6, 2000); 43005 (June 30, 2000), 65 FR 42411 (July 10, 2000); 44099 (March 23, 2001), 66 FR 17457 (March 30, 2001); and 44348 (May 24, 2001), 66 FR 29610 (May 31, 2001).

[8] The Plan defines ''eligible security'' as any Nasdaq/NM security as to which unlisted trading privileges have been granted to a national securities exchange pursuant to Section 12(f) of the Act or that is listed on a national securities exchange. On May 12, 1999, in response to a request from the CHX, the Commission expanded the number of eligible Nasdaq/NM securities that may be traded by the CHX pursuant to the Plan from 500 to 1000. *See* May 1999 Approval Order, *supra* note 7. On November 9, 2000, the Commission noticed and requested comment on a proposal by the PCX to expand the maximum number of securities eligible to trade to include all Nasdaq/NM securities. *See* Securities Exchange Act Release No. 43545, 65 FR 69581 (November 17, 2000).

[9] The full text of the Plan, as well as a ''Concept Paper'' describing the requirements of the Plan, are contained in the original filing, which is available for inspection and copying in the Commission's public reference room.

[10] 17 CFR 240.11Ac1–2.

[11] Rule 11Ac1–2 under the Act requires that the best bid or best offer be computed on a price/size/time algorithm in certain circumstances. Specifically, Rule 11Ac1–2 under the Act provides that ''in the event two or more reporting market centers make available identical bids or offers for a reported security, the best bid or offer * * * shall be computed by ranking all such identical bids or offers * * * first by size * * * Then by time.'' The exemption permits vendors to display the BBO for Nasdaq securities subject to the Plan on a price/time/size basis.

[12] 17 CFR 11Aa3–1.

[13] 15 U.S.C. 78k–1.

[14] In approving this extension, the Commission has considered the extension's impact on efficiency, competition, and capital formation. 15 U.S.C. 78(c)(f).

[15] *See supra* note 4. The Commission notes that the SuperMontage order stated the Participants were directed to produce a revised plan by July 19, 2001. The Commission, however, provided for a 3-month extension of the July 19, 2001 deadline if requested by the Participants for good cause. The

Continued

Participants represent in their proposal that they have unanimously approved an Interim Plan, and are in the process of getting the requisite Boards' signatures for submission of the proposed Interim Plan to the Commission. Further, the Participants represent that they will make a concerted effort to submit the proposed Interim Plan that would include a process for selecting an alternative securities information processor by July 19, 2001. In light of the current negotiations regarding the existing Plan and the representations of the Participants in their request to the Commission, the Commission approves the requested extension of the Plan until August 20, 2001.

The Commission notes that the revised Plan must provide for either (1) a fully viable alternative exclusive securities information processor (''SIP'') for all Nasdaq securities, or (2) a fully viable alternative non-exclusive SIP in the event that the Plan does not provide for an exclusive SIP. If the revised Plan provides for an exclusive consolidating SIP, a function currently performed by Nasdaq, the Commission believes that, to avoid conflicts of interest, there should be a presumption that a Plan Participant, and in particular Nasdaq, should not operate such exclusive consolidating SIP. The presumption may be overcome if: (1) The Plan processor is chosen on the basis of bona fide competitive bidding and the Participant submits the successful bid; and (2) any decision to award a contract to a Plan Participant, and any ensuing review or renewal of such contract, is made without that Plan participant's direct or indirect voting participation. If a Plan Participant is chosen to operate such exclusive SIP, the Commission believes there should be a further presumption that the Participant-operated exclusive SIP shall operate completely separate from any order matching facility operated by that Participant and that any order matching facility operated by that Participant must interact with the plan-operated SIP on the same terms and conditions as any other market center trading Nasdaq-listed securities. Further, the Commission will expect the NASD to provide direct or indirect access to the alternative SIP, whether exclusive or non-exclusive, by any of its members that qualify, and to disseminate transaction information and individually identified quotation information for these members through the SIP.

Furthermore, the revised Plan should be open to all SROs, and the Plan should share governance of all matters subject to the Plan equitably among the SRO Participants. The Plan also should provide for sharing of market data revenues among SRO Participants. Finally, the Plan should provide a role for participation in decision making to non-SROs that have direct or indirect access to the alternative SIP provided by the NASD. The Commission expects the parties to continue to negotiate in good faith on the above matters [16] as well as any other issues that arise during Plan negotiations.

The Commission also finds that it is appropriate to extend the exemptive relief from Rule 11Ac1–2 [17] under the Act until the earlier of August 20, 2001, or until such time as the calculation methodology of the BBO is based on a mutual agreement among the Participants approved by the Commission. The Commission further finds that it is appropriate to extend the exemptive relief from Rule 11Aa3–1 [18] under the Act to the BSE through August 20, 2001. The Commission believes that the temporary extensions of the exemptive relief provided to vendors and the BSE, respectively, are consistent with the Act, the Rules thereunder, and specifically with the objectives set forth in Sections 12(f) [19] and 11A [20] of the Act and in Rules 11Aa3–1 [21] and 11Aa3–2 [22] thereunder.

VII. Conclusion

It is Therefore Ordered, pursuant to Sections 12(f) [23] and 11A [24] of the Act and paragraph (c)(2) of Rule 11Aa3–2 [25] thereunder, that the Participants' request to extend the effectiveness of the Plan, as amended, for Nasdaq/NM securities traded on an exchange on an unlisted or listed basis through August 20, 2001, and certain exemptive relief through August 20, 2001, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[26]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–18067 Filed 7–18–01; 8:45 am]

BILLING CODE 8010–01–M

Commission recognizes that the Participants have been meeting to discuss the alternatives for a new plan.

[16] *See also* discussion in the SuperMontage order, *supra* note 4.

[17] 17 CFR 24011Ac1–2.

[18] 17 CFR 240.11Aa3–1.

[19] 15 U.S.C. 78*l*(f).

[20] 15 U.S.C. 78k–1.

[21] 17 CFR 240.11Aa3–1.

[22] 17 CFR 240.11Aa3–2.

[23] 15 U.S.C. 78*l*(f).

[24] 15 U.S.C. 78k–1.

[25] 17 CFR 240.11Aa3–2(c)(2).

[26] 17 CFR 200.30–3(a)(29).

SECURITIES AND EXCHANGE COMMISSION

[Release 34–44553; File No. 600–23]

Self-Regulatory Organizations; Government Securities Clearing Corporation; Notice of Filing and Order Approving an Extension of Temporary Registration as a Clearing Agency

July 13, 2001.

The Securities and Exchange Commission (''Commission'') is publishing this notice and order to solicit comments from interested persons and to extend the Government Securities Clearing Corporation's (''GSCC'') temporary registration as a clearing agency through December 31, 2001. On May 24, 1988, pursuant to Sections 17A(b) and 19(a) of the Act [1] and Rule 17Ab2–1 promulgated thereunder,[2] the Commission granted GSCC registration as a clearing agency on a temporary basis for a period of three yrars.[3] The Commission subsequently has extended GSCC's registration through July 31, 2001.[4]

The Commission today is extending GSCC's temporary registration as a clearing agency in order that GSCC may continue to act as a clearing agency while the Commission seeks comment on granting GSCC permanent registration as a clearing agency. The Commission expects to publish notice requesting comments on permanent registration as a clearing agency during the third quarter of this year.

Interested persons are invited to submit written data, views, and arguments concerning the foregoing application. Such written data, views, and arguments will be considered by the Commission in granting registration or

[1] 15 U.S.C. 78q–1(b) and 78s(a).

[2] 17 CFR 240.17Ab2–1.

[3] Securities Exchange Act release No. 25740 (May 24, 1988), 53 FR 19639.

[4] Securities Exchange Act Release Nos. 25740 (May 24, 1988), 53 R 19639; 29236 (May 24, 1991), 56 FR 24852; 32385 (June 3, 1993), 58 FR 32405; 35787 (May 31, 1995), 60 FR 30324; 36508 (November 27, 1995), 60 FR 61719; 37983 (November 25, 1996), 61 FR 64183; 38698 (May 30, 1997), 62 FR 30911; 39696 (February 24, 1998), 63 FR 10253; 41104 (February 24, 1999), 64 FR 10510; 41805 (August 27, 1999), 64 FR 48682; 42335 (January 12, 2000), 65 FR 3509; 43089 (July 28, 2000), 65 FR 48032; and 43900 (January 29, 2001), 66 FR 8988.

instituting proceedings to determine whether registration should be denied in accordance with Section 19(a)(1) of the Act.[5] Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 fifth Street, NW., Washington, DC 20549–0609. Copies of the application for registration and all written comments will be available for inspection at the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549–0102. All submissions should refer to File No. 600–23 and should be submitted by August 9, 2001.

It is therefore ordered that GSCC's temporary registration as a clearing agency (File No. 600–23) be and hereby is extended through December 31, 2001.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–18066 Filed 7–18–01; 8:45 am]

BILLING CODE 8010–01–01

[5] 15 U.S.C. 78s(a)(1).

[6] 17 CFR 200.30–3(a)(16).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44554; File No. SR–NYSE–2001–19]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the New York Stock Exchange, Inc. Relating to Closed End Fund Listing Fees

July 13, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] (''Act'') and Rule 19b-4 thereunder,[2] notice is hereby given that on July 6, 2001, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which items have been prepared by the NYSE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to cap the total listing fees payable by any one family of closed-end funds, with respect to new or additional listings in 2001, once the family has paid 2001 fees aggregating at least $1,250,00.

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 NYSE included statements concerning the purpose of, and basis for, the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in Sections A, B, and C below.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Most closed end investment companies, or closed end funds, that are listed on the Exchange are sponsored by one of a number of companies that specialize in this area. Many of these are household names such as Morgan Stanley Van Kampen; Nuveen; or Merrill Lynch Asset Management, to name the three with the largest number of closed end funds listed on the NYSE. The Exchange is actively engaged in reviewing the listing fees that we charge to closed end funds, and will likely propose a maximum that will apply to the aggregate of initial and annual fees paid by all the funds affiliated with a particular fund sponsor, or ''family.'' While Exchange management has not completed this review and is not yet ready to put forward a definitive proposal, it is far enough along to consider it appropriate to put in place a maximum that will apply for the remainder of this year, so that fund families can be confident that additional listings this year will not incur fees beyond the level at which we anticipate a cap will be enacted.

Accordingly, from and after the effective date of this proposal, no fund family will be required to pay any additional listing fees with respect to new or additional listings in 2001 once the family has paid 2001 fees aggregating at least $1,250,000. A family that has paid aggregate fees in excess of that amount prior to the effective date hereof will not receive a refund, but will not be required to pay any additional fees with respect to this year beyond what it has paid to that date.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(4)[3] that an Exchange have rules that provide for the equitable allocation of reasonable dues, fees and other charges among its members and issuers and other persons using its facilities.

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.

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 foregoing proposed rule: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[4] and subparagraph (f)(6) of Rule 19b–4 thereunder.[5]

The Commission notes that under Rule 19b–4(f)(6)(iii),[6] the proposal does not become operative for 30 days after date of its filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. The Exchange requested that the Commission designate that the proposed rule change does not become operative for 15 days after the date of its filing so that the benefits of the proposed rule change are available to closed end funds more quickly. The Commission believes that designating the operative date of the proposal for 15 days after the date of the proposal's filing is consistent with the protection of investors and the public interest.[7]

At any time within 60 days of the filing of the proposed rule change, as amended, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f(b)(4).

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(6)(iii).

[6] 17 CFR 240.19b–4(f)(6).

[7] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

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 proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549–0609.

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 will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to the SR–NYSE–2001–19 and should be submitted by August 9, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–18065 Filed 7–18–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44551; File No. SR–PCX–2001–14]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change and Amendment Nos. 1 and 2 Thereto by the Pacific Exchange, Inc. Relating to Generic Listing Standards Applicable to the Listing and Trading of Investment Company Units and Portfolio Depositary Receipts Pursuant to Rule 19b–4(e) Under the Securities Exchange Act of 1934

July 12, 2001.

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 May 1, 2001, the Pacific Exchange, Inc. (''PCX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change, as described in Items I and II below, which Items have been prepared by the Exchange. On June 19, 2001, the Exchange filed Amendment No. 1 to the proposed rule change.[3] On July 12, 2001, the Exchange filed Amendment No. 2 to the proposed rule change.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and to approve the proposal, as amended, on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its listing requirements for ICUs and PDRs to permit its wholly-owned subsidiary PCX Equities, Inc. (''PCXE'' or ''Corporation'') to list and trade, or trade pursuant to unlisted trading privileges ''UTP''), certain products of ICUs (PCXE Rule 5) or PDRs (PCXE Rule 8) pursuant to Rule 19b–4(e) under the Act.[5] The Exchange also proposes a related amendment to PCXE's minimum price variation rule (PCXE Rule 7, Commentary .05).[6] The text of the proposed rule change is available upon request from the Office of the Secretary, the Commission, or the PCX.

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's current rules for the initial and continued listing of ICUs and PDRs are set forth in PCXE Rules 5.2(j)(3)[7] and 8.100,[8] respectively.[9] The exchange proposes to amend these rules by adopting generic listing requirements to provide standards that permit the trading, whether by listing or pursuant to unlisted trading privileges (''UTP''),[10] of various ICUs and PDRs products pursuant to Rule 19b–4(e) under the Act.[11] The Exchange believes that the Commission's approval of the proposed generic listing requirements for ICUs and PDRs will allow PCXE to begin trading qualifying products without the need for notice and comment and commission approval. The Exchange further believes that application of Rule 19b–4(e) to these securities potentially reduces the time frame for bringing these securities to the market and thus enhances investors' opportunities.

The Commission has previously approved requests by the American Stock Exchange LLC (''Amex''), Chicago Stock Exchange, Inc. (''CHX'') and the Chicago Board Options Exchange, Inc. (''CBOE'') to provide generic standards to list and trade ICUs and PDRs.[12] The Exchange believes that

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Letter from Peter D. Bloom, Director, Regulatory Projects, Regulatory Policy, PCX, to Lisa N. Jones, Attorney, Division of Market Regulation (''Division''), Commission (June 18, 2001) (''Amendment No. 1''). Amendment No. 1, among other things, revises the proposal to: (1) Modify the initial listing requirement of the minimum number of Units, that may be outstanding at commencemnt of trading to 100,000 Units, consistent with the other exchanges; (2) amend the proposed rule text language relating to minimum price variations for Investment Company Units (''Units'') and Portfolio Depositary Receipts (''PDRs''); and (3) amend proposed rule text and adds cross-references for clarification purposes.

[4] *See* Letter from Cindy Sink, Senior Attorney, Regulatory Policy, PCX, to Lisa N. Jones, Attorney, Division, Commission (July 12, 2001) (''Amendment No. 2''). Amendment No. 2 corrects typographical errors to the proposed rule text.

[5] 17 CFR 240.19b–4(e). Rule 19b–4(e) permits self-regulatory organizations (''SROs'') to list and trade new derivatives products that comply with existing SRO trading rules, procedures, surveillance programs and listing standards, without submitting a proposed rule change under Section 19(b). *See* Securities Exchange Act Release No. 40761 (December 8, 1998) 63 FR 70952 (December 22, 1998).

[6] *See* note 3, *supra.*

[7] The Exchange's definition of ''Unit'' for ICUs is contained in PCXE Rule 5.1(b)(5).

[8] the Exchange's definition of a ''PDR'' is contained in PCXE Rule 8.100(a).

[9] *See* Securities Exchange Act Release No. 39461 (December 17, 1997), 62 FR 67674 (December 29, 1997) (approving SR–PCX–97–35 relating to listing and trading criteria for PDRs) and Securities Exchange Act Release No. 41983 (October 6, 1999), 64 FR 56008 (October 15, 1999) (approving SR–PCX–98–29 relating to listing and trading criteria for ICUs).

[10] *See* 17 CFR 240.12f–5.

[11] *See* note 4, *supra.*

[12] *See* Securities Exchange Act Release No. 42787 (May 15, 2000), 65 FR 33598 (May 24, 2000) (approving SR–Amex–00–14 relating to the generic listing standards for PDRs and Index Fund Shares); Securities Exchange Act Release No. 42975 (June 22, 2000), 65 FR 40712 (June 30, 2000) (approving SR–CHX–00–14 relating to generic listing standards for ICUs and PDRs); and Securities Exchange Act Release No. 44046 (March 7, 2001), 66 FR 15152

the proposed generic listing requirements for ICUs and PDRs are substantially similar to the listing requirements at the Amex, CHX and CBOE.

Criteria for Initial and Continued Listing and Trading. The Exchange is proposing to implement generic listing requirements that are intended to ensure that a substantial portion of the weight of an index or portfolio underling ICUs or PDRs is composed of securities with substantial market capitalization and trading volume. The Exchange proposed to amend its current listing standards for a series of ICUs or PDRs, contained in PCXE Rules 5.2(j)(3) and 8.100, respectively, to provide standards that permit the listing and trading, or trading pursuant to UTP, of various ICUs or PDRs products, pursuant to Rule 19b–4(e) under the listing requirements as described below.

Upon the initial listing of a serious ICUs or PDRs, the Exchange proposes that the component stocks contained in the aggregate account for at least 90% of the weight of the underlying index or portfolio must have a minimum market value of at least $75 million. In addition, the component stocks representing at least 90% of the weight of the index or portfolio must have a minimum monthly trading volume during each of the last six months of at least 250,000 shares. The most heavily weighted component stock in an underlying index or portfolio cannot exceed 25% of the weight of the index or portfolio, and the five most heavily weighted component stocks cannot together exceed 65% of the weight of the index or portfolio must include a minimum of 13 stocks,[13] and all securities in an underlying index or portfolio must be listed on a national securities exchange or the Nasdaq Stock Market (including, the Nasdaq SmallCap Market). Furthermore, the Exchange proposes that any series of ICUs or PDRs traded pursuant to generic listing requirements must meet these eligibility criteria as the date of initial deposit of securities and cash into the trust or fund.

Under the proposed amendments to PCXE Rules 5.2(j)(3) (for ICUs) and 8.100 (for PDRs), the underlying index or portfolio must be calculated based on either the market capitalization, modified market capitalization, price, equal-dollar or modified equal-dollar weighting methodology. In addition, if the index 8is maintained by a broker-dealer, the broker-dealer must erect a ''fire-wall'' around the personnel who have access to information concerning changes and adjustments to the index or portfolio, and the index must be calculated by a third party who is not a broker-dealer.

The hours during which ICUs transactions may be made on the Exchange are 6:30 a.m. (Pacific Time (''PT'') until 1:30 p.m. (PT) for each series of Units. The hours during which PDRs transactions may be made on the Exchange are 6:30 (PT) until 1:30 p.m. (PT) for each series of PDRs.

The current index value must be disseminated every 15 seconds over the Consolidated Tape Association's Network, as well as an estimate of the net asset value per share of each series of ICUs or PDRs.[14] Additionally, the Reporting Authority must disseminate for each series of ICUs or PDRs an estimate, updated every 15 seconds, of the value of a share of each series. This estimate may be based, for example, upon current information regarding the required deposit of securities and cash amount to permit creation of new shares of the series or upon the index value.

A series of ICUs or PDRs will be registered in book-entry form through the Depository Trust Company. A minimum of 100,000 shares of a series of ICUs or PDRs is required to be outstanding at the time trading begins. The Exchange represents that it believes that this minimum number is sufficient to establish a liquid Exchange market at the start of trading. The minimum price variation for quoting and entry of orders in a series of ICUs or PDRs will be $0.01.

PCXE Rules Applicable to Trading of ICUs and PDRs. The Exchange proposes to trade ICUs and PDRs pursuant to the PCXE's existing equity trading rules. Specifically, all series of ICUs and PDRs listed under Rule 19b–4(e) will be subject to PCXE's general dealing and settlement rules, including its rules on clearance and settlement of securities transactions and its equity margin rules. Other generally applicable PCXE equity rules and procedures will also apply, including, among others, rules governing the Intermarket Trading System, priority of orders, operational and regulatory trading halts, and responsibilities of specialists.

The Exchange will implement written surveillance procedures for the ICUs and PDRs that it trades pursuant to Rule 19b–4(e). The Exchange intends to use its existing surveillance technology and procedures adopted for PDRs[15] to conduct surveillance of trading activity in series of ICUs or PDRs. The Exchange believes these procedures will effectively monitor the trading activity in ICU or PDR products so as to ensure full compliance with Exchange rules and the federal securities laws. In addition, the Exchange will comply with the recordkeeping requirements of Rule 19b–4(e),[16] and will file Form 19b–4(e) for each series of ICUs or PDRs within five business days of commencement of trading.

Notice to Members and Member Organizations.[17] The Exchange proposes to issue and distribute an information circular to its members and member organizations for each series of ICUs or PDRs to be listed pursuant to Rule 19b–4(e). The circular will describe the special characteristics of the securities and will inform members or member organizations of any obligation to deliver a written product description prospectus, as applicable, to purchasers of ICUs or PDRs. In addition, the circular will inform members or member organizations that all series of ICUs and PDRs listed under Rule 19b–4(e) will be subject to Exchange procedures and rules comparable to those applied to existing products.

Disclosure to Customers. The proposed rule amendment requires members and member organizations to provide purchasers of a series of ICUs with a product description of the terms and characteristics of such securities in a form approved by the Corporation or prepared by the open-end management investment company issuing the securities, not later than the time a confirmation of the first transaction in such series is delivered to the

(March 15, 2001) (approving SR–CBOE–00–51 relating to generic listing standards for Index Portfolio Shares (''ISPs'') and Index Portfolio Receipts (''IPRs'')).

[13] Thirteen stocks is the minimum number to permit qualification as a regulated investment company under Subchapter M of the Internal Revenue Code. Under Subchapter M of the Internal Revenue Code, for a fund to qualify as a regulated investment company the securities of a single issuer can account for no more than 25% of a fund's total assets, and at least 50% of a fund's total assets and must be comprised of cash (including government securities) and securities of single issuers whose securities account for less than 5% of the fund's total assets.

[14] The PCX notes the information described in this section will be disseminated by or through the primary exchange or another entity working with that exchange.

[15] PCXE currently trades, pursuant to unlisted trading privileges, PDRs based on the S&P 500 Index, the S&P MidCap 400 Index, and the Nasdaq-100 Index.

[16] 17 CFR 240.19b–4(e).

[17] Under PCX Equities, Inc. rules, the terms ''ETP Holder,'' ''Equity ASAP Holder'' and ''ETP Firm'' have status as a ''member'' of the PCX as that term is defined in Section 3 of the Act. Therefore, for purposes of this rule filing notice, the terms ''member'' and ''member organization'' are synonymous with the terms ETP Holder, Equity ASAP Holder and ETP Firm, if applicable.

purchaser.[18] This requirement applies only if the particular series has been granted relief from the prospectus delivery requirements of Section 24(d) of the Investment Company Act of 1940,[19] and are not otherwise subject to prospectus delivery requirements under the Securities Act of 1933. In addition, members and member organizations are required to include the product description with any sales materials relating to a series of ICUs that are provided to the public. Any other written materials provided to customers by a member or member organization referring to a series of ICUs must include a statement relating to the product description, in substantially the form set forth in the proposed amendment to PCXE Rule 5.2(j)(3).

The Exchange also proposes to amend PCXE Rule 8.100(c) to clarify that the disclosure provisions of this subparagraph are only applicable to a series of PDRs if, among other things, that series is not subject to prospectus delivery requirements under the Securities Act of 1933.[20] In addition, the Exchange proposes to amend PCXE Rule 8.100(c) to provide that the descriptive disclosure document required by this Rule must be in a form approved by the Exchange or prepared by the unit investment trust issuing the subject PDRs.[21]

The proposal also provides that a member or member organization carrying an omnibus account for a non-ETP Holder, non-Equity ASAP Holder, or non-ETP Firm is required to inform such non-ETP Holder, non-Equity ASAP Holder, or non-ETP Firm that execution of an order to purchase a series of ICUs for such account will be deemed to constitute agreement by the non-member to make such product description available to its customers on the same terms as are directly applicable to members and member organizations under the proposed amendment to PCXE Rule 5.2(j)(3). The proposal also requires that a member or member organization must provide a prospectus for a particular series of ICUs upon the customer's request.

Definition of Reporting Authority. The Exchange proposes to adopt proposed PCXE Rule 5.1(b)(16) that defines the term ''Reporting Authority.'' This definition was adapted from PCXE Rule 8.100(a)(2) and is intended to ensure uniformity in the use of this term in the rules pertaining to both ICUs and PDRs.

Moreover, under proposed PCXE Rule 5.2(j)(3)(D), specific limitations of liability are provided to protect the Exchange, index proprietors, calculators and vendors. The proposed rules also state that there are no express or implied warranties with respect to ICUs. The Exchange represents that these provisions are based on similar provisions already contained in the rules of the Exchange regarding PDRs.[22]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b)[23] of the Act, in general, and furthers the objectives of Section (b)(5),[24] in particular, in that it is designed to promote just and equitable principles of trade, to enhance competition and 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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

The Exchange did not receive any 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, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. 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 will also be available for inspection and copying at the principal office of the PCX. All submissions should refer to File No. SR–PCX–2001–14 and should be submitted by August 9, 2001.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b)(5) of the Act.[25] Specifically, the Commission finds that the PCX proposal to establish generic listing standards to permit the listing and trading of ICUs and PDRs pursuant to Rule 19b–4(e) furthers the intent of that rule by facilitating commencement of trading in these securities without the need for notice and comment and Commission approval under Section 19(b) of the Act. Thus, by establishing generic listing standards, the proposal should reduce the Exchange's regulatory burden, as well as benefit the public interest, by enabling the Exchange to bring qualifying products to the market more quickly. Accordingly, the Commission finds that the Exchange's proposal will promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, and, in general, protect investors and the public interest consistent with Section 6(b)(5) of the Act.[26]

In general, ICUs represent an interest in a registered investment company that holds securities based on, or representing an interest in, an index or portfolio of securities. The Exchange currently trades a number of securities pursuant to UTP under its ICU and PDR listing standards.[27]

[18] The Exchange notes that the current PCXE Rule 8.100 relating to the listing and trading of PDRs already requires its ETP Holders, Equity ASAP Holders and ETP Firms to provide all purchasers of a series of PDRs a written description of the terms and characteristics of such securities, in a form approved by the Corporation. *See* PCXE Rule 8.100(c).

[19] 15 U.S.C. 80a–24(d).

[20] *Id.*

[21] PCXE Rule 8.100(c) currently states that the descriptive disclosure document required by this Rule must be in a form approved by the Corporation only.

[22] *See* PCXE Rule 8.100(f).

[23] 15 U.S.C. 78f(b).

[24] 15 U.S.C. 78f(b)(5).

[25] 15 U.S.C. 78f(b)(5).

[26] *Id.* In approving this rule, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[27] *See* note 11, *supra.* These listing standards are similar to those maintained by other exchanges. *See, e.g.,* Amex Rules 1000 (Portfolio Depositary Receipts) and 1000A (Index Fund Shares).

PDRs, in contrast, represent interests in a unit investment trust that holds securities, which comprise an index or portfolio. Each trust is intended to provide investors with an instrument that closely tracks the underlying securities index or portfolio, that trades like a share of common stock, and that pays holders a periodic cash payment proportionate to the dividends paid, on the underlying portfolio of securities, less certain expenses, as described in the applicable trust prospectus.

Rule 19b–4(e) provides that the listing and trading of a new derivative securities product by an 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 Act, the SRO's trading rules, procedures and listing standards for the product class that include the new derivative securities product and the SRO has a surveillance program for the product class.[28]

As noted above, the Commission has previously approved PCX rules that permit the listing and trading of ICUs and PDRs. In approving these securities for trading, the Commission considered the structure of these securities, their usefulness to investors and to the markets, and the PCX rules that govern their trading. Moreover, the Exchange has separately filed proposed rule changes pursuant to Rule 19b–4 for each of the series of ICUs or PDRs currently trading on the Exchange.

The Commission's approval of the proposed generic listing standards for these securities will allow those series of PDRs and ICUs that satisfy those standards to start trading under Rule 19b–4(e), without the need for notice and comment and Commission approval. The Exchange's ability to rely on Rule 19b–4(e) for these products potentially reduces the time frame for bringing these securities to the market or for permitting the trading of these securities pursuant to UTP, and thus enhances investors' opportunities. The Commission notes that while the proposal reduces the Exchange's regulatory burden, the Commission maintains regulatory oversight over any products listed under the generic standards through regular inspection oversight.

The Commission previously concluded that PDRs and ICUs trading under the existing Exchange rules would allow investors to: (1) Respond quickly to market changes through intra-day trading opportunities; (2) engage in hedging strategies similar to those used by institutional investors; and (3) reduce transactions costs for trading a portfolio of securities.[29] The Commission believes, for the reasons set forth below, that the product classes that satisfy the proposed generic standards for PDRs and ICUs should produce the same benefits to investors.

The Commission also finds that the proposal contains adequate rules and procedures to govern the trading of PDRs and ICUs under Rule 19b–4(e). All series of PDRs and ICUs listed under the generic standards will be subject to the full panoply of PCXE rules and procedures that now govern the trading of existing PDRs and ICUs on the Exchange or pursuant to UTP. Accordingly, any new series of PDRs and ICUs listed and traded under Rule 19b–4(e) will be subject to PCXE rules governing the trading of equity securities, including, among others, rules and procedures governing trading halts, disclosures to members, responsibilities of the specialist, account opening and customer suitability requirements, the election of a stop or limit order, and margin.

In addition, the Exchange has developed specific listing criteria for series of PDRs or ICUs qualifying for Rule 19b–4(e) treatment that will help to ensure that a minimum level of liquidity will exist to allow for the maintenance of fair and orderly markets. Specifically, the proposed generic listing standards require that a minimum of 100,000 shares of a series of PDRs or ICUs is outstanding as of the start of trading. The Commission believes that this minimum number of securities is sufficient to establish a liquid Exchange market at the commencement of trading.

The Commission believes that the proposed generic listing standards ensure that the securities composing the indexes and portfolios underlying the ICUs and PDRs are well capitalized and actively traded. These capitalization and liquidity criteria serve to prevent fraudulent or manipulative acts and are therefore consistent with Section 6(b)(5) of the Act.

In addition, as previously noted, all series of PDRs and ICUs listed or traded under the generic standards will be subject to the Exchange's existing continuing listing criteria. This requirement allows the PCX to consider the suspension of trading and the delisting of a series if an event occurs that makes further dealings in such securities inadvisable. The Commission believes that this will give the PCX flexibility to delist PDRs or ICUs if circumstances warrant such action.

Furthermore, the Commission finds that the Exchange's proposal to trade ICUs or PDRs in minimum price variations of $0.01 is consistent with the Act. The Commission believes that such trading should enhance market liquidity, and should promote more accurate pricing, tighter quotations, and reduced price fluctuations, all of which benefit the investor. The Commission also believes that such trading should allow customers to receive the best possible execution of their transactions in the PDRs or ICUs, thereby protecting customers and the public interest consistent with Section 6(b)(5) of the Act.[30]

The Commission believes that the hours of trading proposed for both ICUs and PDRs transactions are reasonable. In addition, the Exchange represents that the Reporting Authority will disseminate for each series of PDRs or ICUs an estimate, updated every 15 seconds, of the value of a share of each series. The Exchange further represents that the information that is reported will be disseminated by or through the primary exchange or another entity working with that exchange, when the PCX trades one of these products pursuant to UTP. The Commission believes that the information the Exchange proposes to have disseminated will provide investors with timely and useful information concerning the value of each series.

The Exchange has developed surveillance procedures for PDRs and ICUs listed under the generic standards that incorporate and rely upon existing PCX surveillance procedures governing PDRs, ICUs, and equities traded on PCXE. The Commission believes that these surveillance procedures are adequate to address concerns associated with listing and trading PDRs and ICUs under the generic standards. Accordingly, the Commission believes that the rules governing the trading of such securities provide adequate safeguards to prevent manipulative acts and practices and to protect investors and the public interest, consistent with Section 6(b)(5) of the Act.[31] The Exchange represents that it will file Form 19b–4(e) with the Commission within five business days of commencement of trading a series under the generic standards, and will comply

[28] *See* Securities Exchange Act Release No. 40761 (December 8, 1998), 63 FR 70952 (December 22, 1998).

[29] *See* Securities Exchange Act Release No. 42787 (May 15, 2000), 65 FR 33598 (May 24, 2000) (approving SR–Amex–00–14); Securities Exchange Act Release No. 42542 (March 17, 2000), 65 FR 16437 (March 28, 2000) (noticing SR–Amex–00–14).

[30] 15 U.S.C. 78f(b)(5).

[31] 15 U.S.C. 78f(b)(5).

with all Rule 19b–4(e) recordkeeping requirements.

The Commission also notes that certain concerns are raised when a broker-dealer is involved in both the development and maintenance of a stock index upon which a product such as PDRs or ICUs is based. The proposal requires that, in such circumstances, the broker-dealer must have procedures in place to prevent the misuse of material, non-public information regarding changes and adjustments to the index and that the index value be calculated by a third party who is not a broker-dealer. The Commission believes that these requirements should help address concerns raised by a broker-dealer's involvement in the management of such an index.

Finally, the Commission believes that the Exchange's proposal will ensure that investors have information that will allow them to be adequately apprised of the terms, characteristics, and risks of trading PDRs and ICUs. Members and member organizations will be required to provide to all purchasers of ICUs or PDRs a written description of the terms and characteristics of these securities, to include their product description in sales materials provided to customers or the public, to include a specific statement relating to the availability of the description in other types of materials distributed to customers or the public, and to provide a copy of the prospectus, when requested by a customer. The proposal also requires a member or member organization carrying an omnibus account for a non-ETP Holder, non-Equity ASAP Holder, or non-ETP Firm, to notify the non-ETP Holder, non-Equity ASAP Holder, or non-ETP Firm that execution of an order to purchase an ICU or PDR constitutes an agreement by the non-member to provide the product description to its customers.

The Commission also notes that upon the initial listing, or trading pursuant to UTP, of any PDRs or ICUs under the generic standards, the Exchange will issue a circular to its members explaining the unique characteristics and risks of this particular type of security. The circular also will note the Exchange members' prospectus or product description delivery requirements, and highlight the characteristics of purchases in a particular series of PDRs or ICUs. The circular also will inform members of these securities. The Commission believes that these requirements ensure adequate disclosure to investor about the terms and characteristics of a particular series and is consistent with section 6(b)(5) of the Act.[32]

The Commission finds good cause for approving the proposed rule change, as amended, prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register** pursuant to Section 19(b)(2) of the Act. The Commission notes that the proposed rule change is based on the generic listing standards in Amex Rule 1000 *et seq.* (PDRs) and 1000A *et seq.* (Index Fund Shares), which the Commission previously approved after soliciting public comment on the proposal pursuant to Section 19(b)(1) of the Act.[33] The Commission does not believe that the proposed rule change raises novel regulatory issues that were not addressed in the Amex filing. Accordingly, the Commission believes it is appropriate to permit investors to benefit from the flexibility afforded by these new instruments by trading them as soon as possible. Accordingly, the Commission finds that there is good cause, consistent with Section 6(b)(5) of the Act,[34] to approve the proposal on an accelerated basis.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[35] that the proposed rule change (SR–PCX–2001–14) and Amendment Nos. 1 and 2 thereto, are hereby approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[36]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–18068 Filed 7–18–01; 8:45 am]

BILLING CODE 8010–01–M

[32] 15 U.S.C. 78f(b)(5).

[33] *See* note 28 *supra.* The Commission notes that the PCX proposal is also based on the generic listing standards at the CHX and the CBOE. *See* note 11, *supra.*

[34] 15 U.S.C. 78s(b)(5).

[35] 15 U.S.C. 78s(b)(2).

[36] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed During Week Ending July 6, 2001

The following Agreements were filed with the Department of Transportation under provisions of 49 U.S.C. 412 and 414. Answers may be filed within 21 days after the filing of the applications.

Docket Number: OST–2001–10051.
Date Filed: July 3, 2001.
Parties: Members of the International Air Transport Association.
Subject:
PTC COMP 0834 dated July 3, 2001
Mail Vote 131—Resolution 010f
Special Passenger Amending Resolution (remove certain exceptional cost increases adopted at the February/November, 2000 meetings)
Intended effective date: July 15, 2001

Dorothy Y. Beard,

Federal Register Liaison.

[FR Doc. 01–18113 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Application for Certificates of Public Convenience and Necessity

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (formerly Subpart Q) during the week ending July 6, 2001. The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 *et seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period, DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: OST–2001–10052.
Date Filed: July 3, 2001.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: July 24, 2001.
Description: Application of DHL Airways, Inc., pursuant to 49 U.S.C. 41102 and subpart B, requesting a renewal and an amendment of its certificate of public convenience and necessity for Route 725, Segments 1 through 6, to provide scheduled foreign air transportation of property and mail between points in the United States and points in Mexico.

Docket Number: OST–2001–10068.
Date Filed: July 6, 2001.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: July 27, 2001.
Description: Application of Amerijet International, Inc., pursuant to 49 U.S.C.

Section 41102 and Subpart B, requesting a renewal and an amendment of its certificate of public convenience and necessity for Route 570, Segment 1 through 4, to provide scheduled foreign air transportation of property and mail between points in the United States and points in Mexico for a five-year period. Amerijet also requests that its certificate authority be amended to include the terminal point Fort Lauderdale, in addition to, or as an alternative to Miami.

Dorothy Y. Beard,

Federal Register Liaison.

[FR Doc. 01–18114 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Environmental Impact Statement for the Baltimore-Washington Maglev Proposal

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of Intent to Prepare an Environmental Impact Statement

SUMMARY: FRA is issuing this notice to advise the public that FRA will prepare an environmental impact statement (EIS) for the Baltimore-Washington Maglev proposal linking the Camden Yards area in Baltimore, MD and Baltimore-Washington International Airport (BWI) with Union Station in Washington, DC; to solicit public and agency input into the development of the EIS; and, to advise the public that outreach activities conducted by the program participants will be considered in the preparation of the EIS.

FOR FURTHER INFORMATION CONTACT: Mr. Suhair Alkhatib, Maryland Mass Transit Administration, William Donald Schaefer Tower, 6 St. Paul Street, Baltimore, MD 21202–1614, Telephone: (410) 767–3751, email: *salkhatib@mdot.state.md.us* or Michael Saunders, Federal Railroad Administration, 628–2 Hebron Avenue, Suite 303, Glastonbury, CT 06033–5007, Telephone: (860) 659–6714, email: *Michael.Saunders@fhwa.dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FRA prepared a programmatic EIS (PEIS) to address the selection process and the potential for significant environmental impact from the maglev deployment program authorized in Section 1218 (23 U.S.C. 322) of the Transportation Equity Act for the 21st Century (TEA 21). The notice of availability of the final PEIS was published in the **Federal Register** on May 4, 2001. In addition, the Maryland Mass Transit Administration prepared an environmental assessment for the Maryland project in February, 2000 which was used by the FRA to assist the agency in preparing the PEIS. The PEIS is available on the FRA website at: *http://www.fra.dot.gov/s/env/maglev/MagPEIS.htm.*

The Secretary of Transportation, consistent with FRA's Maglev Deployment Program regulation (49 CFR Part 268), selected two locations (including this proposal) for further analysis and the development of a site specific EIS. This could lead to the selection of a single project for Federal capital assistance for construction, depending on the appropriation of funds by the U.S. Congress.

The FRA, in cooperation with the Maryland Mass Transit Administration, will prepare a site-specific EIS on a proposal to build a Maglev project linking downtown Baltimore to BWI Airport and Union Station in Washington DC. The FRA, in cooperation with the Port Authority of Allegheny County, Pennsylvania, will also prepare a site-specific EIS for the other location selected for further analysis and development.

It is anticipated that the EIS will consider alternatives including: (1) yaking no action, and (2) various alignment and station locations from downtown Baltimore to BWI Airport and Union Station in Washington, DC, and possibly a Capital Beltway station.

Scoping and Comments

FRA encourages broad participation in the EIS process and review of the resulting environmental documents. Comments and suggestions related to the project and potential environmental concerns are invited from all interested agencies and the public at large to ensure that the full range of issues related to the proposed action and all reasonable alternatives are addressed and all significant issues are identified. The public will be invited to participate in the scoping process, review the Draft EIS, and provide input at public meetings. Letters describing the proposed scope of the EIS and soliciting comments will be sent to appropriate Federal, State and local agencies, elected officials, community organizations, and to private organizations and citizens who have previously expressed interest in this proposal. Several public meetings to be advertised in the local media will be held in the project area regarding this proposal. Release of the Draft EIS for public comment and public meetings and hearings will be announced as those dates are established.

Comments or questions concerning this notice of intent and the EIS should be directed to the FRA or the Maryland Mass Transit Administration at the addresses noted above.

Issued in Washington DC on: July 13, 2001.

Arrigo P. Mongini,

Deputy Associate Administrator for Railroad Development, Federal Railroad Administration.

[FR Doc. 01–18111 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Environmental Impact Statement for Pennsylvania Maglev Proposal

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: FRA is issuing this notice to advise the public that FRA will prepare an environmental impact statement (EIS) for the Pennsylvania Maglev proposal linking Pittsburgh International Airport to Pittsburgh and its eastern suburbs in Allegheny and Westmoreland Counties; to solicit public and agency input into the development of the EIS; and, to advise the public that outreach activities conducted by the program participants will be considered in the preparation of the EIS.

FOR FURTHER INFORMATION CONTACT: Mr. Bruce W. Ahern, Port Authority of Allegheny County, 2235 Beaver Avenue, Pittsburgh, PA 15233–1080, Telephone: (412) 237–6121, email *Bahern@PortAuthority.org* or Michael Saunders, Federal Railroad Administration, 628–2 Hebron Avenue, Suite 303, Glastonbury, CT 06033–5007, Telephone: (860) 659–6714, email *Michael.Saunders@fhwa.dot.gov*

SUPPLEMENTARY INFORMATION:

Background

The FRA prepared a programmatic EIS (PEIS) to address the selection process and the potential for significant environmental impact from the maglev deployment program authorized in Section 1218 (23 U.S.C. 322) of the Transportation Equity Act for the 21st Century (TEA 21). The notice of availability of the final PEIS was published in the **Federal Register** on

May 4, 2001. In addition, the Port Authority of Allegheny County prepared an environmental assessment for the Pennsylvania project in February, 2000 which was used by the FRA to assist the agency in preparing the PEIS. The PEIS is available on the FRA website at: *http://www.fra.dot.gov/s/env/maglev/MagPEIS.htm.*

The Secretary of Transportation, consistent with FRA's Maglev Deployment Program regulation (49 CFR part 268), selected two locations (including this proposal) for further analysis and the development of a site specific EIS. This could lead to the selection of a single project for Federal capital assistance for construction, depending on the appropriation of funds by the U.S. Congress.

The FRA, in cooperation with the Port Authority of Allegheny County, will prepare a site-specific EIS on a proposal to build a Maglev project linking Pittsburgh International Airport to Pittsburgh and its eastern suburbs. The FRA, in cooperation with the Maryland Mass Transit Administration, will also prepare a site-specific EIS for the other location selected for further analysis and development.

It is anticipated that the EIS will consider alternatives including: (1) Taking no action, and (2) various alignment and station locations from the airport to downtown Pittsburgh and the eastern suburbs of Monroeville and Greensburg.

Scoping and Comments

FRA encourages broad participation in the EIS process and review of the resulting environmental documents. Comments and suggestions related to the project and potential environmental concerns are invited from all interested agencies and the public at large to ensure that the full range of issues related to the proposed action and all reasonable alternatives are addressed and all significant issues are identified. The public will be invited to participate in the scoping process, review the draft EIS, and provide input at public meetings. Letters describing the proposed scope of the EIS and soliciting comments will be sent to appropriate Federal, State and local agencies, elected officials, community organizations, and to private organizations and citizens who have previously expressed interest in this proposal. Several public meetings to be advertised in the local media will be held in the project area regarding this proposal. Release of the draft EIS for public comment and public meetings and hearings will be announced as those dates are established.

Comments or questions concerning this notice of intent and the EIS should be directed to the FRA or the Port Authority of Allegheny County at the addresses noted above.

Issued in Washington DC on: July 13, 2001.

Arrigo P. Mongini,

Deputy Associate Administrator for Railroad Development, Federal Railroad Administration.

[FR Doc. 01–18112 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2001–9947]

Notice of Receipt of Petition for Decision that Nonconforming 2000–2001 Mercedes Benz S500 and S600 Passenger Cars Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 2000–2001 Mercedes Benz S500 and S600 passenger cars are eligible for importation.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 2000–2001 Mercedes Benz S500 and S600 passenger cars that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATE: The closing date for comments on the petition is August 20, 2001.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW., Washington, DC 20590. [Docket hours are from 9 a.m. to 5 p.m.].

FOR FURTHER INFORMATION CONTACT: George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR Part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

J.K. Technologies of Baltimore, Maryland (''J.K.'') (Registered Importer 90–006) has petitioned NHTSA to decide whether 2000–2001 Mercedes Benz S500 and S600 passenger cars are eligible for importation into the United States. The vehicles which J.K. believes are substantially similar are 2000–2001 Mercedes Benz S500 and S600 passenger cars that were manufactured for importation into, and sale in, the United States and certified by their manufacturer as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 2000–2001 Mercedes Benz S500 and S600 passenger cars to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

J.K. submitted information with its petition intended to demonstrate that non-U.S. certified 2000–2001 Mercedes Benz S500 and S600 passenger cars, as originally manufactured for sale in Europe, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 2000–2001 Mercedes Benz S500 and S600 passenger cars are identical to their U.S. certified counterparts with respect to compliance with Standard Nos. 102 *Transmission Shift Lever Sequence * * * * *,* 103 *Defrosting and Defogging Systems,* 104 *Windshield Wiping and Washing Systems,* 105 *Hydraulic Brake Systems,* 106 *Brake Hoses,* 109 *New Pneumatic Tires,* 113 *Hood Latch Systems,* 116 *Brake Fluid,* 124 *Accelerator Control Systems,* 202 *Head Restraints,* 204 *Steering Control Rearward Displacement,* 205 *Glazing Materials,* 206 *Door Locks and Door Retention Components,* 207 *Seating Systems,* 209 *Seat Belt Assemblies,* 210 *Seat Belt Assembly Anchorages,* 212 *Windshield Retention,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* 301 *Fuel System Integrity,* and 302 *Flammability of Interior Materials,* as well as 49 CFR Part 581.

The petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:* (a) Substitution of the word ''Brake'' for the international ECE warning symbol on the markings for the brake failure indicator lamp; (b) replacement of the speedometer with one calibrated in miles per hour. The petitioner states that the entire instrument cluster will be replaced with a U.S.-model component.

Standard No. 108 Lamps, *Reflective Devices and Associated Equipment:* (a) installation of U.S.-model headlamps and front sidemarker lamps, (b) installation of U.S.-model taillamp assemblies which incorporate rear sidemarker lamps and (c) installation of U.S.-model high-mounted stop light assembly (if necessary).

Standard No. 110 *Tire Selection and Rims:* installation of a tire information placard.

Standard No. 111 *Rearview Mirror:* replacement of the passenger side rearview mirror with a U.S.-model component.

Standard No. 114 *Theft Protection:* Installation of a warning buzzer and a warning buzzer microswitch in the steering lock assembly.

Standard No. 118 *Power Window Systems:* installation of a relay in the power window system so that the window transport is inoperative when the ignition is switched off on vehicles that are not already so equipped.

Standard No. 201 *Occupant Protection in Interior Impact:* Inspect each vehicle and replace any non-U.S. model parts with U.S. model parts.

Standard No. 208 *Occupant Crash Protection:* (a) Installation of a seat belt warning buzzer, wired to the driver's seat belt latch; (b) inspection of all vehicles and replacement of the driver's and passenger's side air bags, knee bolsters, control units, sensors, and seat belts with U.S.-model components on vehicles that are not already so equipped. The front and rear outboard designated seating positions have combination lap and shoulder belts that are self-tensioning and that release by means of a single red pushbutton.

Standard No. 214 *Side Impact Protection:* Inspect vehicles and replace any non-complying part with U.S. model parts.

The petitioner also states that a vehicle identification plate must be affixed to the vehicles near the left windshield post and a reference and certification label must be affixed in the area of the left front door post to meet the requirements of 49 CFR Part 565.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9 am to 5 pm]. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: July 13, 2001.

Marilynne Jacobs,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 01–17994 Filed 7–18–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Termination; Highlands Insurance Company, Highland Underwriters Insurance Company

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 22 to the Treasury Department Circular 570; 2000 Revision, published June 30, 2000 at 65 FR 40868.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6765.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Certificates of Authority issued by the Treasury to the above named Companies, under the United States Code, Title 31, Sections 9304–9308, to qualify as an acceptable sureties on Federal bonds is terminated effective today.

The Companies were last listed as an acceptable sureties on Federal bonds at 65 FR 40886, June 30, 2000.

With respect to any bonds, including continuous bonds, currently in force with above listed Companies, bond-approving officers should secure new bonds with acceptable sureties in those instances where a significant amount of liability remains outstanding. In addition, in no event, should bonds that are continuous in nature be renewed.

The Circular may be viewed and downloaded through the Internet at http://www.fms.treas.gov/c570/index.html. A hard copy may be purchased from the Government Printing Office (GPO), Subscription Service, Washington, DC, telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 048–000–00536–5.

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financing Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6A04, Hyattsville, MD 20782.

Dated: June 30, 2001.

Judith R. Tillman,

Assistant Commissioner, Financial Operations, Financial Management Service.

[FR Doc. 01–18101 Filed 7–18–01; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[EE–43–92]

Proposed Collection: Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The department of the Treasury, as part of its continuing effort

to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, EE–43–92 (TD 8619), Direct Rollovers and 20-Percent Withholding Upon Eligible Rollover Distributions From Qualified Plans (§§ 1.401(a)(31)–1, 1.402(c)–2, 1.402(f)–1, 1.403(b)–2, and 31.3405(c)–1).

DATES: Written comments should be received on or before September 17, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Larnice Mack, (202) 622–3179, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Direct Rollovers and 20-Percent Withholding Upon Eligible Rollover Distributions From Qualified Plans.

OMB Number: 1545–1341.

Regulation Project Number: EE–43–92.

Abstract: This regulation implements the provisions of the Unemployment Compensation Amendments of 1992 (Pub. L. 102–318), which impose mandatory 20 percent income tax withholding upon the taxable portion of certain distributions from a qualified pension plan or a tax-sheltered annuity that can be rolled over tax-free to another eligible retirement plan unless such amounts are transferred directly to such other plan in a ''direct rollover'' transaction. These provisions also require qualified pension plans and tax-sheltered annuities to offer their participants the option to elect to make ''direct rollovers'' of their distributions and to provide distributees with a written explanation of the tax laws regarding their distributions and their option to elect such a rollover.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals, business or other for-profit organizations, not-for-profit institutions, and Federal, state, local or tribal governments.

Estimated Number of Respondents: 10,323,926.

Estimated Time Per Respondent: 13 minutes.

Estimated Total Annual Burden Hours: 2,129,669.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 16, 2001.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 01–18127 Filed 7–18–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0060]

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 process beneficiaries claims for payment of insurance proceeds.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before September 17, 2001.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0060'' in any correspondence.

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., 3501–3520), 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.

Titles:

a. Claim For Government Life Insurance Policy, VA Form Letter 29–764.

b. Claim For One Sum Payment (Government Life Insurance), VA Form 29–4125.

c. Claim For Monthly Payments (National Service Life Insurance), VA Form 29–4125a.

d. Claim For One Sum Payment (Govt. Life Insurance All Prefixes), VA Form 29–4125b.

e. Claim For Monthly Payments (United States Government. Life Insurance, (USGLI)), VA Form 29–4125k.

OMB Control Number: 2900–0060.

Type of Review: Extension of a currently approved collection.

Abstract: VA forms and form letter are used by beneficiaries to apply for proceeds of Government Insurance policies. The collected information is used by VA to process beneficiaries claim for payment of insurance proceeds.

Affected Public: Individuals or households.

Estimated Annual Burden: 8,938 hours.

a. FL 29–764—100 hours.
b. VA Form 29–4125—8,200 hours.
c. VA Form 29–4125a—463 hours.
d. VA Form 29–4125b—50 hours.
e. VA Form 4125k—125 hours.

Estimated average burden per respondent:

a. FL 29–764—6 minutes.
b. VA Form 29–4125—6 minutes.
c. VA Form 29–4125a—15 minutes.
d. VA Form 29–4125b—6 minutes.
e. VA Form 4125k—15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 85,850.

a. FL 29–764—1,000.
b. VA Form 29–4125—82,000.
c. VA Form 29–4125a—1,850.
d. VA From 29–4125b—500.
e. VA Form 4125k—500.

Dated: June 28, 2001.

By direction of the Secretary.

Barbara H. Epps,

Management Analyst, Information Management Service.

[FR Doc. 01–17999 Filed 7–18–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0586]

Agency Information Collection Activities Under OMB Review

AGENCY: Office of Acquisition and Materiel Management, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C., 3501 *et seq.*), this notice announces that the Office of Acquisition and Materiel Management, 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 August 20, 2001.

FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT: Denise McLamb, Information Management Service (045A4), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 273–8030 or FAX (202) 273–5981 or e-mail to: *denise.mclamb@mail.va.gov*. Please refer to ''OMB Control No. 2900–0586'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Title: Veterans Affairs Acquisition Regulation (VAAR) Clause 852.211–75, Technical Industry Standards.

OMB Control Number: 2900–0586.

Type of Review: Reinstatement, without change, of a previously approved collection for which approval has expired.

Abstract: VAAR clause 852.211–75, Technical Industry Standards, requires that items offered for sale to VA under solicitation conform to certain technical industry standards, such as Underwriters Laboratory (UL) or the National Fire Protection Association and that the contractor furnish evidence to VA that the items meet that requirement. The evidence is normally in the form of a tag or seal affixed to the item, such as the UL tag on an electrical cord or a tag on a fire-rated door. This requires no additional effort on the part of the contractor, as items come from the factory with tags already in place, as part of the manufacturer's standard manufacturing operation. Occasionally, for items not already meeting standards or for items not previously tested, a contractor will have to furnish a certificate from an acceptable laboratory certifying that the items furnished have been tested in accordance with, and conform to, specified standards. Only firms whose products have not previously been tested to ensure the products meet industry standards required under solicitation will be required to submit a separate certificate. The information will be used to ensure that items being purchased meet minimum safety standards and to protect VA employees, VA beneficiaries and the public.

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 April 11, 2001, at page 18853.

Affected Public: Business or other for profit, individuals or households, and not-for-profit institutions.

Estimated Annual Burden: 50 hours.

Estimated Average Burden Per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 100.

Send comments and recommendations concerning any aspect of the information collection 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. 2900–0586'' in any correspondence.

Dated: June 28, 2001.

By direction of the Secretary.

Barbara H. Epps,

Management Analyst, Information Management Service.

[FR Doc. 01–18000 Filed 7–18–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0593]

Agency Information Collection Activities Under OMB Review

AGENCY: Office of Acquisition and Materiel Management, Department of Veterans Affairs

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C., 3501 *et seq.*), this notice announces that the Office of Acquisition and Materiel Management, 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.

DATE: Comments must be submitted on or before August 20, 2001.

FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT: Denise McLamb, Information Management Service (045A4), Department of Veterans Affairs, 8l0 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030 or FAX (202) 273–5981 or e-mail to: *denise.mclamb@mail.va.gov*. Please refer to ''OMB Control No. 2900–0593'' in any correspondence.

SUPPLEMENTARY INFORMATION: *Title*: Veterans Affairs Acquisition Regulation (VAAR) Provision 852.214–70, Caution to Bidders '' Bid Envelopes.

OMB Control Number: 2900–0593.

Type of Review: Reinstatement, without change, of a previously approved collection for which approval has expired.

Abstract: VAAR Provision 852.214–70, Caution to Bidders '' Bid Envelopes, advises bidders that it is their responsibility to ensure that their bid price cannot be ascertained by anyone prior to bid opening. It also advises bidders to identify their bids by showing the invitation number and bid opening date on the outside of the bid envelope. The Government often furnished a blank bid envelope or a label for use by bidders/offers to identify their bids. The bidder is advised to fill in the required information. This information requested from bidders is needed by the Government to identify bid envelopes from other mail or packages received without having to open the envelopes or packages and possibly exposing bid prices before bid opening. The information will be used to identify which parcels or envelopes are bids and which are other routine mail. The information is also needed to help ensure that bids are delivered to the proper bid opening room on time and prior to bid opening.

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 March 27, 2001, at pages 16704–16705.

Affected Public: Business or other for profit, individuals or households, and not-for-profit institutions.

Estimated Annual Burden: 960 hours.

Estimated Average Burden Per Respondent: 10 seconds.

Frequency of Response: On occasion.

Estimated Number of Respondents: 346,000.

Send comments and recommendations concerning any aspect of the information collection 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. 2900–0593'' in any correspondence.

Dated: June 28, 2001.

By direction of the Secretary.

Barbara H. Epps,

Management Analyst, Information Management Service.

[FR Doc. 01–18001 Filed 7–18–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Rehabilitation Research and Development Service Scientific Merit Review Board, Notice of Meeting

The Department of Veterans Affairs gives notice under Public Law 92–463 (Federal Advisory Committee Act) as amended, by section 5(c) of Public Law 94–409 that a meeting of the Rehabilitation Research and Development Service Scientific Merit Review Board will be held at the Crown Plaza Hotel, 1001 14th Street, NW., Washington, DC on July 31 through August 1, 2001.

The sessions on July 31, and August 1, 2001, are scheduled to begin at 8:30 a.m. and end at 5 p.m. The purpose of the meeting is to review rehabilitation research and development applications for scientific and technical merit and to make recommendations to the Director, Rehabilitation Research and Development Service, regarding their funding.

The meeting will be open to the public for the July 31 session from 8:30 a.m. to 9 a.m. for the discussion of administrative matters, the general status of the program, and the administrative details of the review process. On July 31 from 9 a.m. through August 1, 2001, the meeting is closed during which the Board will be reviewed research and development applications.

This review involves oral comments, discussion of site visits, staff and consultant critiques of proposed research protocols, and similar analytical documents that necessitate the consideration of the personal qualifications, performance and competence of individual research investigators. Disclosure of such information would constitute a clearly unwarranted invasion of personal privacy. Disclosure would also reveal research proposals and research underway which could lead to the loss of these projects to third parties and thereby frustrate future agency research efforts.

Thus, the closing is in accordance with 5 U.S.C. 552b(c)(6), and (c)(9)(B) and the determination of the Secretary of the Department of Veterans Affairs under sections 10(d) of Public Law 92–463 as amended by section 5(c) of Public Law 94–409.

Those who plan to attend the open session should write to Ms. Victoria Mongiardo, Program Analyst, Rehabilitation Research and Development Service (122P), Department of Veterans Affairs, 810 Vermont Ave. NW., Washington, DC 20420 (Phone: 202–408–3684) at least five days before the meeting.

Dated: July 5, 2001.

By Direction of the Secretary.

Ronald R. Aument,

Acting Committee Management Officer.

[FR Doc. 01–18002 Filed 7–18–01; 8:45 am]

BILLING CODE 8320–01–M

Federal Register

Thursday,
July 19, 2001

Part II

General Services Administration

41 CFR Parts 101–6 and 102–3

Federal Advisory Committee Management; Final Rule

GENERAL SERVICES ADMINISTRATION

41 CFR Parts 101–6 and 102–3

[FPMR Amendment A–57]

RIN 3090–AG49

Federal Advisory Committee Management

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is revising Federal Property Management Regulations (FPMR) coverage on Federal advisory committee management and moving it into the Federal Management Regulation (FMR). A cross-reference is added to the FPMR to direct readers to the coverage in the FMR. The FMR coverage is written in plain language to provide agencies with updated regulatory material that is easy to read and understand. This action is necessary due to legislative and policy changes that have occurred, and judicial decisions that have been issued since the regulation was last updated. It is based also on suggestions for improvement from other Federal agencies and interested parties, and clarifies how the regulation applies or does not apply to certain situations.

EFFECTIVE DATE: August 20, 2001.

FOR FURTHER INFORMATION CONTACT: Charles F. Howton, Deputy Director, Committee Management Secretariat (202) 273–3561, or electronically at the following Internet address: *charles.howton@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

GSA's authority for administering the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. (also referred to as ''the Act''), is contained in section 7 of the Act and Executive Order 12024 (42 FR 61445; 3 CFR 1977 Comp., p. 158). Under Executive Order 12024, the President delegated to the Administrator of General Services all of the functions vested in the President by the Act. GSA's responsibilities for administering the Act have been delegated to the Associate Administrator for Governmentwide Policy and to the Director of the Committee Management Secretariat.

In a previous issue of the **Federal Register** (62 FR 31550, June 10, 1997), GSA published an Advance Notice of Proposed Rulemaking (ANPRM) and requested comments. Additional comments were requested from the Interagency Committee on Federal Advisory Committee Management. GSA requested comments on: (1) Suggested issues to address; (2) specific recommendations about changes needed in the current Federal Advisory Committee Management subpart; (3) examples of situations where FACA was either a useful tool or a hindrance to public involvement; and (4) GSA's intent to include illustrative examples and principles. On January 14, 2000, GSA published a proposed rule in the **Federal Register** (65 FR 2504) and requested comments over a 60-day period ending on March 14, 2000. All comments received were considered in drafting this final rule.

This final rule provides administrative and interpretive guidelines and management controls for Federal agencies to implement the provisions of the Act, and is intended to improve the management and operation of Federal advisory committees in the executive branch.

B. Discussion of Comments

Twenty-six commenters responded to the invitation for comments, including twenty commenters from the executive branch and six commenters from non-Federal sources. Of the twenty comments received from executive branch sources, three comments were submitted by subcomponents of a Federal department or agency. A total of fifty-nine specific issues or recommendations were identified, of which seven were either fully supportive of the proposed rule or concerned typographical errors. GSA addressed the disposition of the remaining fifty-two issues or recommendations as follows:

The Final Rule Should Include More Guidance Relating to the Management of Advisory Committees, Including the Impact of Other Statutes and Issues on Day-to-Day Operations

Several commenters provided suggestions regarding the addition of guidance on issues that, although not addressed by the Act, likely would improve the management of advisory committees. For example, one commenter suggested that the final rule include a provision to encourage agencies to streamline their internal processes and procedures in order to expedite the establishment of advisory committees. Other commenters requested that GSA: (1) Provide more detailed provisions on the compensation of advisory committee members and staff, and experts and consultants; (2) expand the range of information required to be listed in an advisory committee's charter to include the nature and disposition of records; and (3) incorporate new regulatory requirements for increasing access to advisory committee information, such as providing meeting notices, minutes, and reports via the Internet.

In response to these recommendations, GSA expanded the number of examples included within the final rule to illustrate how other statutes or issues potentially could affect the effective management of advisory committees.

In addition, GSA reorganized the examples and other guidance into appendices to avoid any ambiguity between actions required by the Act and the final rule, and actions that are suggested only within an implementing framework of ''best practices.'' In the final rule, a ''Key Points and Principles'' appendix appears at the end of each subpart to which it relates.

In applying the ''best practices'' offered in the appendices, users of the final rule should continue to examine the extent to which other factors, including agency-specific statutory provisions and internal agency procedures, may affect a specific advisory committee or program. Although GSA believes that the examples contained in the appendices to the final rule represent the circumstances most commonly encountered during the day-to-day management of advisory committees, the listing is not exhaustive and must be supplemented based upon the unique requirements of the user.

Provide Additional Guidance Regarding What Advisory Committees and Their Subcommittees Must Do To Comply With the Act

Many commenters expressed concern over language contained in the preamble to the proposed rule relating to coverage of subcommittees under the Act. The preamble to the proposed rule noted that:

> The applicability of the procedural requirements contained in FACA and this proposed rule to subcommittees of advisory committees has been clarified. GSA's current FACA regulation does not make clear that subcommittees reporting to a parent committee are not subject to FACA. Indeed, the regulation states just the opposite, providing that ''[s]ubcommittees that do not function independently of the full or parent advisory committee'' are subject to all requirements of FACA except the requirement for a charter. (See 41 CFR 101–6.1007(b)(3).) This provision is problematic for two reasons. First, it applies FACA more broadly than the statute itself requires. Second, it essentially creates a special type

of advisory committee that is subject to some, but not all of FACA's requirements, which has no foundation in the statute. Under FACA, a group is either an advisory committee subject to all of the statutory requirements, or it is not an advisory committee, and therefore not subject to any of its requirements. Because a subcommittee which reports to a parent committee is not an ''advisory committee'' under FACA, there is no legal basis for applying any of FACA's requirements to such a subcommittee.

In evaluating the comments received, GSA notes that there were no objections to the exclusions contained in § 102–3.185 of the proposed rule (now § 102–3.160 of the final rule), relating to ''What activities of an advisory committee are not subject to the notice and open meeting requirements of the Act?'' The exclusions in § 102–3.160 of the final rule continue to cover the types of activities routinely performed by subcommittees. By this reasoning GSA sought to bring into harmony these activities with those provisions in the proposed rule differentiating subcommittees reporting to a parent advisory committee from those reporting directly to a Federal officer or agency.

However, the preamble to the proposed rule did not explain and describe adequately the legal framework for GSA's decision to differentiate subcommittees that report only to a parent advisory committee more clearly from advisory committees that report directly to a Federal officer or agency. The Act defines the term ''advisory committee'' as ''any committee, * * * or any subcommittee or other subgroup thereof which is established or utilized by the President or an agency in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government''. Under this definition, a subcommittee is an ''advisory committee'' subject to the Act if it provides advice to the President or a Federal officer or agency. Most subcommittees, however, report only to a parent advisory committee and it is the parent committee that is normally responsible for providing advice or recommendations to the Government. In this conventional scenario, the subcommittee is not subject to the Act because it is not providing advice to the Government.

Case law supports this conclusion. In *National Anti-Hunger Coalition* v. *Executive Committee,* 557 F.Supp. 524 (D.D.C.), *aff'd,* 711 F.2d 1071 (D.C. Cir. 1983), the question presented was whether the Act applied to task forces reporting to the Executive Committee of the President's Private Sector Survey on Cost Control in the Federal Government. The task forces had no authority to make recommendations to agencies or to the President. Instead, their function was to do the ''preliminary work of the survey, including fact-gathering, statistical evaluations, and the formulation of preliminary reports.'' (557 F.Supp. at 526). Although it was undisputed that the Executive Committee was subject to the Act, the court held that the Act did not apply to the task forces under the following reasoning:

There is no question that the task forces are intimately involved in the gathering of information about federal programs and the formulation of possible recommendations for consideration of the Committee. That is not enough to render them subject to the FACA. The Act itself applies only to committees ''established or utilized by'' the President or an agency ''in the interest of obtaining advice or recommendations for the President or one or more agencies.'' The Act does not cover groups performing staff functions such as those performed by the so-called task forces. (557 F.Supp. at 529). (See also *Association of American Physicians and Surgeons* v. *Clinton,* 997 F.2d 898, 911–913 (D.C. Cir. 1993).)

GSA believes that as a result of this decision, subcommittees that report to a parent advisory committee generally are not subject to the Act. GSA also believes that subcommittees whose advice or recommendations are provided directly to a Federal officer or agency are subject to the Act. However, GSA further believes that this decision does not shield those subcommittees from coverage under the Act whose advice or recommendations are not subject to deliberation by their parent advisory committees.

From this reasoning, it is not permissible for parent advisory committees simply to ''rubber-stamp'' the advice or recommendations of their subcommittees, thereby depriving the public of its opportunity to know about, and participate contemporaneously in, an advisory committee's deliberations. Agencies are cautioned to avoid excluding the public from attending any meeting where a subcommittee develops advice or recommendations that are not expected to be reviewed and considered by the parent advisory committee before being submitted to a Federal officer or agency. These exclusions may run counter to the provisions of the Act that require contemporaneous access to the advisory committee deliberative process.

To address these issues more clearly, GSA strengthened language in the final rule by: (1) Adding a new § 102–3.35 that outlines policies relating to subcommittees; (2) clarifying language in § 102–3.145 relating to subcommittee meetings; and (3) clarifying the examples contained in Appendix A to Subpart C.

Correct and Clarify the Definition of ''Utilized''

Nine commenters recommended that GSA revise its definition of the term, ''utilized'' to conform to governing case law.

As noted by some of the commenters, the definition of the term ''utilized'' in § 102–3.30 of the proposed rule inadvertently misstated the applicable legal test. The proposed rule stated that a committee is ''utilized within the meaning of the Act when the President or a Federal agency exercises actual management and control over its operation.'' This construction would require an agency both to have management of the committee and to exercise control over the committee before the committee can be deemed ''utilized.'' The proper statement of the ''utilized'' test is whether an agency either has management of the committee *or,* in some fashion other than management, exercises control over the committee.

The controlling legal authority is *Washington Legal Foundation* v. *U. . Sentencing Commission,* 17 F.3d 1446 (D.C. Cir. 1994). In that case, the appeals court gave structure to the U.S. Supreme Court's prior decision interpreting the term ''utilized.'' (See *Public Citizen* v. *Department of Justice,* 491 U.S. 440 (1989).) The appeals court ruled that the word ''*utilized*'' indicates ''*something along the lines of actual management or control of the advisory committee.*'' (17 F.3d at 1450). The operative criterion for determining whether a committee has sufficiently close ties to an agency in order to render it ''utilized'' is whether the agency has either *management* of the committee or exerts some other type of *control,* but not necessarily both.

Similarly, § 102–3.50(b) of the proposed rule (now § 102–3.185(b) of the final rule) used the phrase ''actual management and control'' with regard to section 15 of the Act. In explaining the relationship between Federal agencies and the National Academy of Sciences (NAS) and the National Academy of Public Administration (NAPA) covered by section 15 of the Act, § 102–3.50(b) of the proposed rule states that ''[a]gencies must not manage or control the specific procedures adopted by each academy.'' However, committees covered by section 15 of the Act must be under *both* the actual management *and* the control of the academies, not that of a Federal agency. In this instance, the use of the conjunctive

word ''and'' is appropriate and indicates that the academies cannot relinquish *either* management or control of their committees to Federal agencies.

Accordingly, GSA revised the language contained in the final rule by changing *management and control* to *management or control* in the definition of the term ''utilized,'' now in § 102–3.25 of the final rule, and in those instances in which it appears in the ''Key Points and Principles'' guidance in the appendices to the final rule.

Clarify the Application of the Act to Agency Interactions With the Public

Several commenters noted that Federal agencies are increasingly reliant on local communities, individual citizens, and interested parties to obtain information, advice, or recommendations on which to base decisions. They expressed concerns that: (1) Uncertainty about the scope of the Act creates a disincentive for Federal officers and agencies wishing to engage in public outreach; (2) the requirements of the Act are being interpreted differently within and among agencies; and (3) GSA's current regulations do not adequately differentiate between those groups and activities covered by the Act and others that are not. (See 41 CFR 101–6.10.)

GSA recognizes that the broad definition in the Act of an ''advisory committee'' might be interpreted to extend coverage by the Act to any gathering or two or more persons from whom the President or other Federal officers or agencies seek advice or recommendations. However, in the cases discussed above, the courts have rejected such a broad reading of ''advisory committee.'' GSA believes that the sections in the final rule on definitions and on groups not covered by the Act, §§ 102–3.25 and 102–3.40, respectively, clarify the limits of the coverage by, or scope of, the Act when applied together.

Within this group of comments, GSA noted a consistent theme related to the need for more information regarding public participation tools and techniques that would allow for more collaboration that is not subject to the Act. Although advisory committees support Federal decisions in a variety of situations, GSA believes that the ability of agencies to interact with the public in numerous other ways is particularly important because advisory committees are only one method for agencies to obtain the views of the public for their programs. Federal agencies may engage in continuous collaboration using diverse, but complimentary, tools, techniques, and methods. Whether or not a selected approach includes the use of advisory committees, the potential or perceived applicability of the Act must not prevent constructive collaboration from taking place. Agencies are encouraged to contact GSA concerning not only the use of Federal advisory committees, but also for information about alternative forms of public involvement.

In GSA's view, agencies have broad latitude to consult with the public using many different approaches that are not subject to the Act. Public consultation formats that generally fall outside of the scope of the Act include public meetings, information exchange forums, meetings initiated with or by non-governmental organizations, Federal participation on groups that are not established or utilized by the Government, and certain work products generated by contractors as a result of consultation with the public.

While FACA is not a public participation statute, it directly affects how the executive branch is held accountable for the use and management of Federal advisory committees as a major means of obtaining public involvement. Within this context, agencies wishing to consult with private individuals, non-governmental organizations, or with the public at large through other assemblages often must consider whether or not the Act applies to a given situation.

The number and range of scenarios presented by the commenters underscore the importance of presenting a clearer understanding of how advisory committees are established by Federal agencies or how the Government's relationship with groups not established within the meaning of the Act may nevertheless become subject to the Act if they are *utilized*. Based upon the comments received, the circumstances under which advisory committees are *established* within the executive branch appear to be well understood. Accordingly, GSA retained the language contained in § 102–3.30 of the proposed rule in § 102–3.25 of the final rule and throughout subpart B.

However, as noted in the above discussion of the proposed rule's treatment of the term ''utilized,'' agencies must determine whether or not their relationship with a group created by non-Federal entities constitutes *actual management or control* within the meaning of the Act. To help agencies make this determination, GSA has included within the final rule several new examples illustrating the application of the *actual management or control* test to different situations. These additions are contained in the ''Key Points and Principles'' guidance in Appendix A to Subpart A.

Explain the Relationship Between Committees Established by the National Academy of Sciences (NAS) or the National Academy of Public Administration (NAPA) and the Act

The Federal Advisory Committee Act Amendments of 1997, Public Law 105–153, December 17, 1997, established separate procedures for committees that are managed and controlled by NAS or NAPA. Subpart E of the final rule contains implementing instructions for the new section 15 of FACA.

Clarify the Distinction Between Advisory Committees Subject to the Act and Operational Committees Not Covered by the Act

Five commenters suggested that further guidance in the final rule is necessary to assist agencies in differentiating an operational committee not covered by the Act from one that performs primarily advisory functions and is, therefore, subject to the Act. GSA added guidance within Appendix A to Subpart A listing those characteristics generally associated with committees having primarily operational, as opposed to advisory, functions.

Clarify the Applicability of the Act to Advisory Committee Meetings Conducted Through Electronic Means

Four commenters supported GSA's language contained in the proposed rule extending the definition of ''committee meeting'' to meetings conducted in whole or part through electronic means. However, two commenters suggested additional clarifications, which GSA has adopted.

First, GSA slightly modified the definition of ''committee meeting'' contained in § 102–3.25 of the final rule to include a ''gathering'' of advisory committee members whether in person or through electronic means. This change was made to highlight coverage by the Act of both physical and ''virtual'' meetings conducted by such means as a teleconference, videoconference, the Internet, or other electronic medium.

Second, GSA amended the language contained in § 102–3.140 of the final rule to provide for adequate public access to advisory committee meetings that are conducted in whole or part through electronic means. This change complements existing policy covering advisory committee meetings that are held within a physical setting, such as a conference room, by ensuring that agencies adequately plan for public

participation by adding additional capability (such as a designated number of public call-in lines for a teleconference) to ensure access to committee deliberations.

Provide Additional Guidance on Balanced Representation and Selection of Members

One commenter expressed concern that the proposed rule did not contain sufficient guidance on balanced representation and the selection of members. GSA recognizes that the guidance contained in the proposed rule is limited to the language of the Act, but believes that the provisions of section 5(c) of the Act are broad enough to allow for agency discretion in determining advisory committee representation and membership relative to applicable statutes, Executive orders, and the needs of the agency responsible for the advisory committee.

However, GSA added a list of possible considerations within Appendix A to Subpart B that, while not comprehensive or universally applicable, may help in developing a plan for balancing an advisory committee's membership.

Emphasize the Importance of Maximizing an Advisory Committee's Independent Judgment

Five commenters offered various suggestions to address the requirement contained in section 5(b)(3) of the Act, which is intended to ensure that the work products of an advisory committee reflect the group's independent judgment.

Included among these suggestions were recommendations from the U.S. Office of Government Ethics (OGE) that GSA modify the language contained in § 102–3.155 of the proposed rule (now contained in Appendix A to Subpart C of the final rule) to clarify the applicability of conflict of interest statutes and other Federal ethics rules to advisory committee members. GSA adopted all of OGE's suggestions.

The remaining suggestions received concerned the appointment of advisory committee members, including a recommended change to § 102–3.155 of the proposed rule (now Appendix A to Subpart C) to clarify that: (1) An agency may appoint a member to an advisory committee based upon the recommendation of an organization to be represented; and (2) recommendations from an advisory committee may be a part of an agency's process to nominate new members. GSA adopted these changes and suggestions.

Provide Additional Guidance on the Management of Federal Records

GSA received suggestions from the National Archives and Records Administration (NARA) regarding three areas where additional guidance on records management issues could be useful. Specifically, NARA recommended that § 102–3.190 of the proposed rule: (1) Be expanded to include all recordkeeping requirements specified by the Act, not just those relating to advisory committee minutes; (2) include a statement that records should be scheduled for disposition before actual termination of the advisory committee; and (3) with regard to information that must be included within an advisory committee's charter, include a determination as to whether its records fall within the Presidential Records Act, 44 U.S.C. Chap 22.

GSA addressed these recommendations by expanding § 102–3.200 of the proposed rule (now Appendix A to Subpart D) to include additional guidance relating to records management and to highlight the applicability and importance of Federal recordkeeping statutes and policies to advisory committee operations. GSA decided to include this guidance within this appendix because the Act generally is silent on records management issues, with the exception of the responsibilities of the CommitteeManagement Officer (CMO) in section 8(b)(2) of the Act.

Pursuant to the National Archives and Records Administration Act, 44 U.S.C.Chap. 21, the Archivist of the United States is responsible for records management in the Federal Government, including the issuance of regulations and guidance for records retention and disposition. The Archivist, working in conjunction with the agencies'' Records Management Officers, also is responsible for identifying records that are appropriate for transfer to the permanent Archives of the United States and those that must be processed in accordance with the Presidential Records Act.

Strengthen Provisions Relating to the Public's Access to Advisory Committee Records

Two commenters suggested that the final rule contain more explicit guidance regarding the public's access to committee records under section 10(b) of the Act. In particular, the commenters recommended adding language describing the circumstances under which records may be withheld pursuant to the Freedom of Information Act (FOIA), as amended, 5 U.S.C. 552.

GSA believes that timely access to advisory committee records is an important element of the public access provisions of the Act and, therefore, agrees with these suggestions. GSA further believes that there are two separate, but equally important issues related to the availability of advisory committee records under section 10(b) of FACA: (1) The extent to which records may be protected from disclosure under FOIA; and (2) the extent to which agencies may require that requests for non-exempt records be processed under the request and review process established by section 552(a)(3) of FOIA.

Section 10(b) of the Act provides that:

> Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

The purpose of section 10(b) of the Act is to provide for the contemporaneous availability of advisory committee records that, when taken in conjunction with the ability to attend advisory committee meetings, ensures that interested parties have a meaningful opportunity to comprehend fully the work undertaken by the advisory committee. Records covered by the exemptions set forth in section 552(b) of FOIA generally may be withheld. However, it should be noted that FOIA Exemption 5 generally cannot be used to withhold documents reflecting an advisory committee's internal deliberations.

An opinion of the Office of Legal Counsel, U.S. Department of Justice, 12 Op. O.L.C. 73, April 29, 1988, entitled ''Disclosure of Advisory Committee Deliberative Materials,'' concludes that FOIA Exemption 5 ''is not generally applicable to materials prepared by or for an advisory committee, but that it does extend to protect privileged documents delivered from the agency to an advisory committee.'' The opinion further states that:

> This construction gives meaning to exemption 5 without vitiating Congress' enumeration of deliberative documents such as working papers and drafts as subject to disclosure. It is also supported by a close reading of exemption 5 itself. Because by its terms exemption 5 protects only inter-agency and intra-agency documents and because an advisory committee is not an agency, documents do not receive the protection of exemption 5 by virtue of the fact that they are prepared by an advisory committee. On

the other hand, documents prepared by an agency do not lose the protection of exemption 5 by virtue of the fact that they are delivered to an advisory committee.

In determining whether or not such records fall within these narrow exclusions, the OLC opinion provides that consideration should be given to determining whether or not section 10(b) of FACA is applicable in the first instance. As noted in the OLC opinion:

> Section 10(b) itself applies only to materials made available to or prepared for or by an advisory committee established by statute or reorganization plan or established or utilized by the President or an agency. 5 U.S.C. app. I, 3(2), 10(b). Accordingly, in determining whether a document is to be disclosed the first issue is not whether it is subject to an exemption under 5 U.S.C. 552 but whether it meets this threshold definition.

In explaining this threshold determination of whether particular records are subject to the section 10(b) disclosure requirement, the OLC opinion states that:

> The courts and this Office have construed the concept of advisory committees established or utilized by the President or an agency to preclude section 10(b)'s application to the work prepared by a staff member of an advisory committee or a staffing entity within an advisory committee, such as an independent task force limited to gathering information, or a subcommittee of the advisory committee that is not itself established or utilized by the President or agency, so long as the material was not used by the committee as a whole.

Although advisory committee records may be withheld under the provisions of FOIA if there is a *reasonable expectation* that the records sought fall within the exemptions contained in section 552(b) of FOIA, agencies may not require members of the public or other interested parties to file requests for non-exempt advisory committee records under the request and review process established by section 552(a)(3) of FOIA.

In *Food Chemical News* v. *Department of Health and Human Services,* 980 F.2d 1468, 299 U.S. App. DC 25, the appeals court held that:

> Under section 10(b) of FACA an agency is generally obligated to make available for public inspection and copying all materials that were made available to or prepared for or by an advisory committee. Except with respect to those materials that the agency reasonably claims to be exempt from disclosure pursuant to FOIA, a member of the public need not request disclosure in order for FACA 10(b) materials to be made available. Thus, whenever practicable, all 10(b) materials must be available for public inspection and copying before or on the date of the advisory committee meeting to which they apply.

Accordingly, GSA included language within § 102–3.170 of the final rule describing the policy to be followed in implementing section 10(b) of the Act, and included additional guidance in Appendix A to Subpart D concerning the applicability of FOIA to records covered by section 10(b) of FACA.

Improve the Organization of the Final Rule

During the course of evaluating comments received from all sources, GSA conducted a review of the proposed rule's general organization and structure for the purpose of achieving greater clarity and consistency in presentation. This effort led to a number of changes, such as redesignating the ''Key Points and Principles'' sections following each subpart as appendices. Other changes were made throughout the final rule to improve alignment between section headings and the material that follows. Similar changes were made within the appendices in order to improve the linkage between the examples or questions and the corresponding guidance.

In addition, GSA reorganized the final rule to redesignate subpart B as subpart E to improve the flow of information distinguishing Federal advisory committees subject to the Act from those committees created by the National Academy of Sciences (NAS) or the National Academy of Public Administration (NAPA) which, if not *utilized* by the executive branch, are not subject to the Act's provisions. Section numbers previously assigned in the proposed rule affected by the redesignation of subpart B as subpart E, subpart C as subpart B, subpart D as subpart C, and subpart E as subpart D have been changed accordingly.

C. Technical and Procedural Comments

The final rule incorporates several technical and procedural recommendations made by a range of commenters, particularly in the following sections or appendices:

Section/Appendix	Modification
102–3.60	Specific procedures for consulting with the Secretariat have been eliminated. GSA will issue separate guidance to agencies covering the administration of the consultation requirement.
Appendix A to Subpart B	Addition of guidance relating to the achievement of ''balanced'' advisory committee membership.
Appendix A to Subpart B	Addition of guidance covering the legal duration of the charter of an advisory committee required by statute where Congress authorizes the advisory committee for a period exceeding two years.
Appendix A to Subpart C	Addition of guidance addressing the designation of an alternate Designated Federal Officer (DFO).
102–3.130	All references to compensation limits imposed by the Act have been updated, and references to alternative similar agency compensation systems other than the General Schedule have been included.
102–3.130	All references to the word, ''handicapped,'' have been replaced with the phrase, ''with disabilities.''
Appendix A to Subpart D	Addition of guidance regarding activities that are not subject to the notice and open meeting requirements of the Act.
102–3.165	The requirement for the completion of advisory committee meeting minutes now requires the DFO to ensure certification within the time limit specified.

D. Consultation With Other Federal Agencies

Pursuant to section 7(d) of the Act, the guidelines contained in this final rule with respect to uniform fair rates of compensation for comparable services of members and staff of, and experts and consultants to advisory committees have been established after consultation with the U.S. Office of Personnel Management (OPM).

Although not required by the Act, the guidelines contained in this final rule that refer to the applicability of conflict of interest statutes and other Federal ethics rules to advisory committee members have been established after consultation with the U.S. Office of Government Ethics (OGE).

Although not required by the Act, the guidelines contained in this final rule that relate to the management of advisory committee records have been established after consultation with the National Archives and Records Administration (NARA).

E. Executive Order 12866

GSA has determined that this final rule is a significant rule for the purposes of Executive Order 12866 of September 30, 1993.

F. Regulatory Flexibility Act

GSA has determined that this final rule will not have a significant economic impact on a substantial number of small entities (including small businesses, small organizational units, and small governmental jurisdictions) within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The rule does not impact small entities and applies only to Federal officers and agencies.

G. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

H. Small Business Regulatory Enforcement Fairness Act

This final rule is being submitted for Congressional review as prescribed under 5 U.S.C. 801.

List of Subjects in 41 CFR Parts 101–6 and 102–3

Advisory committees, Government property management.

Dated: July 5, 2001.

Stephen A. Perry,

Administrator of General Services.

For the reasons set forth in the preamble, GSA amends 41 CFR chapters 101 and 102 as follows:

CHAPTER 101—[AMENDED]

PART 101–6—MISCELLANEOUS REGULATIONS

1. Subpart 101–6.10 is revised to read as follows:

Subpart 101–6.10—Federal Advisory Committee Management

Authority: Sec. 205(c), 63 Stat. 390 (40 U.S.C. 486(c)); sec. 7, 5 U.S.C., App.; and E.O. 12024, 3 CFR, 1977 Comp., p. 158.

§ 101–6.1001 Cross-reference to the Federal Management Regulation (FMR) (41 CFR chapter 102, parts 102–1 through 102–220).

For Federal advisory committee management information previously contained in this subpart, see FMR part 102–3 (41 CFR part 102–3).

CHAPTER 102—[AMENDED]

2. Part 102–3 is added to subchapter A of chapter 102 to read as follows:

PART 102–3—FEDERAL ADVISORY COMMITTEE MANAGEMENT

Subpart A—What Policies Apply To Advisory Committees Established Within the Executive Branch?

Sec.

102–3.5 What does this subpart cover and how does it apply?
102–3.10 What is the purpose of the Federal Advisory Committee Act?
102–3.15 Who are the intended users of this part?
102–3.20 How does this part meet the needs of its audience?
102–3.25 What definitions apply to this part?
102–3.30 What policies govern the use of advisory committees?
102–3.35 What policies govern the use of subcommittees?
102–3.40 What types of committees or groups are not covered by the Act and this part?
Appendix A to Subpart A of Part 102–3—Key Points and Principles

Subpart B—How Are Advisory Committees Established, Renewed, Reestablished, and Terminated?

102–3.45 What does this subpart cover and how does it apply?
102–3.50 What are the authorities for establishing advisory committees?
102–3.55 What rules apply to the duration of an advisory committee?
102–3.60 What procedures are required to establish, renew, or reestablish a discretionary advisory committee?
102–3.65 What are the public notification requirements for discretionary advisory committees?
102–3.70 What are the charter filing requirements?
102–3.75 What information must be included in the charter of an advisory committee?
102–3.80 How are minor charter amendments accomplished?
102–3.85 How are major charter amendments accomplished?
Appendix A to Subpart B of Part 102–3—Key Points and Principles

Subpart C—How Are Advisory Committees Managed?

102–3.90 What does this subpart cover and how does it apply?
102–3.95 What principles apply to the management of advisory committees?
102–3.100 What are the responsibilities and functions of GSA?
102–3.105 What are the responsibilities of an agency head?
102–3.110 What are the responsibilities of a chairperson of an independent Presidential advisory committee?
102–3.115 What are the responsibilities and functions of an agency Committee Management Officer (CMO)?
102–3.120 What are the responsibilities and functions of a Designated Federal Officer (DFO)?
102–3.125 How should agencies consider the roles of advisory committee members and staff?
102–3.130 What policies apply to the appointment, and compensation or reimbursement of advisory committee members, staff, and experts and consultants?
Appendix A to Subpart C of Part 102–3—Key Points and Principles

Subpart D—Advisory Committee Meeting and Recordkeeping Procedures

102–3.135 What does this subpart cover and how does it apply?
102–3.140 What policies apply to advisory committee meetings?
102–3.145 What policies apply to subcommittee meetings?
102–3.150 How are advisory committee meetings announced to the public?
102–3.155 How are advisory committee meetings closed to the public?
102–3.160 What activities of an advisory committee are not subject to the notice and open meeting requirements of the Act?
102–3.165 How are advisory committee meetings documented?
102–3.170 How does an interested party obtain access to advisory committee records?
102–3.175 What are the reporting and recordkeeping requirements for an advisory committee?
Appendix A to Subpart D of Part 102–3—Key Points and Principles

Subpart E—How Does This Subpart Apply to Advice or Recommendations Provided to Agencies by the National Academy of Sciences or the National Academy of Public Administration?

102–3.180 What does this subpart cover and how does it apply?
102–3.185 What does this subpart require agencies to do?
Appendix A to Subpart E of Part 102–3—Key Points and Principles

Authority: Sec. 205(c), 63 Stat. 390 (40 U.S.C. 486(c)); sec. 7, 5 U.S.C., App.; and E.O. 12024, 3 CFR, 1977 Comp., p. 158.

Subpart A—What Policies Apply to Advisory Committees Established Within the Executive Branch?

§ 102–3.5 What does this subpart cover and how does it apply?

This subpart provides the policy framework that must be used by agency heads in applying the Federal Advisory Committee Act (FACA), as amended (or ''the Act''), 5 U.S.C., App., to advisory committees they establish and operate. In addition to listing key definitions underlying the interpretation of the Act, this subpart establishes the scope and applicability of the Act, and outlines specific exclusions from its coverage.

§ 102–3.10 What is the purpose of the Federal Advisory Committee Act?

FACA governs the establishment, operation, and termination of advisory committees within the executive branch of the Federal Government. The Act defines what constitutes a Federal advisory committee and provides general procedures for the executive branch to follow for the operation of these advisory committees. In addition, the Act is designed to assure that the Congress and the public are kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees.

§ 102–3.15 Who are the intended users of this part?

(a) The primary users of this Federal Advisory Committee Management part are:

(1) Executive branch officials and others outside Government currently involved with an established advisory committee;

(2) Executive branch officials who seek to establish or utilize an advisory committee;

(3) Executive branch officials and others outside Government who have decided to pursue, or who are already engaged in, a form of public involvement or consultation and want to avoid inadvertently violating the Act; and

(4) Field personnel of Federal agencies who are increasingly involved with the public as part of their efforts to increase collaboration and improve customer service.

(b) Other types of end-users of this part include individuals and organizations outside of the executive branch who seek to understand and interpret the Act, or are seeking additional guidance.

§ 102–3.20 How does this part meet the needs of its audience?

This Federal Advisory Committee Management part meets the general and specific needs of its audience by addressing the following issues and related topics:

(a) *Scope and applicability.* This part provides guidance on the threshold issue of what constitutes an advisory committee and clarifies the limits of coverage by the Act for the benefit of the intended users of this part.

(b) *Policies and guidelines.* This part defines the policies, establishes minimum requirements, and provides guidance to Federal officers and agencies for the establishment, operation, administration, and duration of advisory committees subject to the Act. This includes reporting requirements that keep Congress and the public informed of the number, purpose, membership, activities, benefits, and costs of these advisory committees. These requirements form the basis for implementing the Act at both the agency and Governmentwide levels.

(c) *Examples and principles.* This part provides summary-level key points and principles at the end of each subpart that provide more clarification on the role of Federal advisory committees in the larger context of public involvement in Federal decisions and activities. This includes a discussion of the applicability of the Act to different decisionmaking scenarios.

§ 102–3.25 What definitions apply to this part?

The following definitions apply to this Federal Advisory Committee Management part:

Act means the Federal Advisory Committee Act, as amended, 5 U.S.C., App.

Administrator means the Administrator of General Services.

Advisory committee subject to the Act, except as specifically exempted by the Act or by other statutes, or as not covered by this part, means any committee, board, commission, council, conference, panel, task force, or other similar group, which is established by statute, or established or utilized by the President or by an agency official, for the purpose of obtaining advice or recommendations for the President or on issues or policies within the scope of an agency official's responsibilities.

Agency has the same meaning as in 5 U.S.C. 551(1).

Committee Management Officer (''CMO''), means the individual designated by the agency head to implement the provisions of section 8(b) of the Act and any delegated responsibilities of the agency head under the Act.

Committee Management Secretariat (''Secretariat''), means the organization established pursuant to section 7(a) of the Act, which is responsible for all matters relating to advisory committees, and carries out the responsibilities of the Administrator under the Act and Executive Order 12024 (3 CFR, 1977 Comp., p. 158).

Committee meeting means any gathering of advisory committee members (whether in person or through electronic means) held with the approval of an agency for the purpose of deliberating on the substantive matters upon which the advisory committee provides advice or recommendations.

Committee member means an individual who serves by appointment or invitation on an advisory committee or subcommittee.

Committee staff means any Federal employee, private individual, or other party (whether under contract or not) who is not a committee member, and who serves in a support capacity to an advisory committee or subcommittee.

Designated Federal Officer (''DFO''), means an individual designated by the agency head, for each advisory committee for which the agency head is responsible, to implement the provisions of sections 10(e) and (f) of the Act and any advisory committee procedures of the agency under the control and supervision of the CMO.

Discretionary advisory committee means any advisory committee that is established under the authority of an agency head or authorized by statute. An advisory committee referenced in general (non-specific) authorizing language or Congressional committee report language is discretionary, and its establishment or termination is within the legal discretion of an agency head.

Independent Presidential advisory committee means any Presidential advisory committee not assigned by the Congress in law, or by President or the President's delegate, to an agency for administrative and other support.

Non-discretionary advisory committee means any advisory committee either required by statute or by Presidential directive. A *non-discretionary advisory committee* required by statute generally is identified specifically in a statute by name, purpose, or functions, and its establishment or termination is beyond the legal discretion of an agency head.

Presidential advisory committee means any advisory committee authorized by the Congress or directed by the President to advise the President.

Subcommittee means a group, generally not subject to the Act, that reports to an advisory committee and not directly to a Federal officer or

agency, whether or not its members are drawn in whole or in part from the parent advisory committee.

Utilized for the purposes of the Act, does not have its ordinary meaning. A committee that is not established by the Federal Government is *utilized* within the meaning of the Act when the President or a Federal office or agency exercises actual management or control over its operation.

§ 102–3.30 What policies govern the use of advisory committees?

The policies to be followed by Federal departments and agencies in establishing and operating advisory committees consistent with the Act are as follows:

(a) *Determination of need in the public interest.* A discretionary advisory committee may be established only when it is essential to the conduct of agency business and when the information to be obtained is not already available through another advisory committee or source within the Federal Government. Reasons for deciding that an advisory committee is needed may include whether:

(1) Advisory committee deliberations will result in the creation or elimination of (or change in) regulations, policies, or guidelines affecting agency business;

(2) The advisory committee will make recommendations resulting in significant improvements in service or reductions in cost; or

(3) The advisory committee's recommendations will provide an important additional perspective or viewpoint affecting agency operations.

(b) *Termination.* An advisory committee must be terminated when:

(1) The stated objectives of the committee have been accomplished;

(2) The subject matter or work of the committee has become obsolete by the passing of time or the assumption of the committee's functions by another entity;

(3) The agency determines that the cost of operation is excessive in relation to the benefits accruing to the Federal Government;

(4) In the case of a discretionary advisory committee, upon the expiration of a period not to exceed two years, unless renewed;

(5) In the case of a non-discretionary advisory committee required by Presidential directive, upon the expiration of a period not to exceed two years, unless renewed by authority of the President; or

(6) In the case of a non-discretionary advisory committee required by statute, upon the expiration of the time explicitly specified in the statute, or implied by operation of the statute.

(c) *Balanced membership.* An advisory committee must be fairly balanced in its membership in terms of the points of view represented and the functions to be performed.

(d) *Open meetings.* Advisory committee meetings must be open to the public except where a closed or partially-closed meeting has been determined proper and consistent with the exemption(s) of the Government in the Sunshine Act, 5 U.S.C. 552b(c), as the basis for closure.

(e) *Advisory functions only.* The function of advisory committees is advisory only, unless specifically provided by statute or Presidential directive.

§ 102–3.35 What policies govern the use of subcommittees?

(a) In general, the requirements of the Act and the policies of this Federal Advisory Committee Management part do not apply to subcommittees of advisory committees that report to a parent advisory committee and not directly to a Federal officer or agency. However, this section does not preclude an agency from applying any provision of the Act and this part to any subcommittee of an advisory committee in any particular instance.

(b) The creation and operation of subcommittees must be approved by the agency establishing the parent advisory committee.

§ 102–3.40 What types of committees or groups are not covered by the Act and this part?

The following are examples of committees or groups that are not covered by the Act or this Federal Advisory Committee Management part:

(a) *Committees created by the National Academy of Sciences (NAS) or the National Academy of Public Administration (NAPA).* Any committee created by NAS or NAPA in accordance with section 15 of the Act, except as otherwise covered by subpart E of this part;

(b) *Advisory committees of the Central Intelligence Agency and the Federal Reserve System.* Any advisory committee established or utilized by the Central Intelligence Agency or the Federal Reserve System;

(c) *Committees exempted by statute.* Any committee specifically exempted from the Act by law;

(d) *Committees not actually managed or controlled by the executive branch.* Any committee or group created by non-Federal entities (such as a contractor or private organization), provided that these committees or groups are not actually managed or controlled by the executive branch;

(e) *Groups assembled to provide individual advice.* Any group that meets with a Federal official(s), including a public meeting, where advice is sought from the attendees on an individual basis and not from the group as a whole;

(f) *Groups assembled to exchange facts or information.* Any group that meets with a Federal official(s) for the purpose of exchanging facts or information;

(g) *Intergovernmental committees.* Any committee composed wholly of full-time or permanent part-time officers or employees of the Federal Government and elected officers of State, local and tribal governments (or their designated employees with authority to act on their behalf), acting in their official capacities. However, the purpose of such a committee must be solely to exchange views, information, or advice relating to the management or implementation of Federal programs established pursuant to statute, that explicitly or inherently share intergovernmental responsibilities or administration (see guidelines issued by the Office of Management and Budget (OMB) on section 204(b) of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1534(b), OMB Memorandum M–95–20, dated September 21, 1995, available from the Committee Management Secretariat (MC), General Services Administration, 1800 F Street, NW., Washington, DC 20405–0002);

(h) *Intragovernmental committees.* Any committee composed wholly of full-time or permanent part-time officers or employees of the Federal Government;

(i) *Local civic groups.* Any local civic group whose primary function is that of rendering a public service with respect to a Federal program;

(j) *Groups established to advise State or local officials.* Any State or local committee, council, board, commission, or similar group established to advise or make recommendations to State or local officials or agencies; and

(k) *Operational committees.* Any committee established to perform primarily operational as opposed to advisory functions. Operational functions are those specifically authorized by statute or Presidential directive, such as making or implementing Government decisions or policy. A committee designated operational may be covered by the Act if it becomes primarily advisory in nature. It is the responsibility of the administering agency to determine whether a committee is primarily operational. If so, it does not fall under

the requirements of the Act and this part.

Appendix A to Subpart A of Part 102–3—Key Points and Principles

This appendix provides additional guidance in the form of answers to frequently asked questions and identifies key points and principles that may be applied to situations not covered elsewhere in this subpart. The guidance follows:

APPENDIX A TO SUBPART A

Key points and principles	Section(s)	Question(s)	Guidance
I. FACA applies to advisory committees that are either ''established'' or ''utilized'' by an agency.	102–3.25, 102–3.40(d), 102–3.40(f)	1. A local citizens group wants to meet with a Federal official(s) to help improve the condition of a forest's trails and quality of concessions. May the Government meet with the group without chartering the group under the Act? 2. May an agency official attend meetings of external groups where advice may be offered to the Government during the course of discussions? 3. May an agency official participate in meetings of groups or organizations as a member without chartering the group under the Act? 4. Is the Act applicable to meetings between agency officials and their contractors, licensees, or other ''private sector program partners?''	A. The answer to questions 1, 2, and 3 is yes, if the agency does not either ''establish'' or ''utilize'' (exercise ''actual management or control'' over) the group. (i) Although there is no precise legal definition of ''actual management or control,'' the following factors may be used by an agency to determine whether or not a group is ''utilized'' within the meaning of the Act: (a) Does the agency manage or control the group's membership or otherwise determine its composition? (b) Does the agency manage or control the group's agenda? (c) Does the agency fund the group's activities? (ii) Answering ''yes'' to any or all of questions 1, 2, or 3 does not automatically mean the group is ''utilized'' within the meaning of the Act. However, an agency may need to reconsider the status of the group under the Act if the relationship in question essentially is indistinguishable from an advisory committee established by the agency. B. The answer to question 4 is no. Agencies often meet with contractors and licensees, individually and as a group, to discuss specific matters involving a contract's solicitation, issuance, and implementation, or an agency's efforts to ensure compliance with its regulations. Such interactions are not subject to the Act because these groups are not ''established'' or ''utilized'' for the purpose of obtaining advice or recommendations.
II. The development of consensus among all or some of the attendees at a public meeting or similar forum does not automatically invoke FACA.	102–3.25, 102–3.40(d), 102–3.40(f)	1. If, during a public meeting of the ''town hall'' type called by an agency, it appears that the audience is achieving consensus, or a common point of view, is this an indication that the meeting is subject to the Act and must be stopped?	A. No, the public meeting need not be stopped. (i) A group must either be ''established'' or ''utilized'' by the executive branch in order for the Act to apply. (ii) Public meetings represent a chance for individuals to voice their opinions and/or share information. In that sense, agencies do not either ''establish'' the assemblage of individuals as an advisory committee or ''utilize'' the attendees as an advisory committee because there are no elements of either ''management'' or ''control'' present or intended.

APPENDIX A TO SUBPART A—Continued

Key points and principles	Section(s)	Question(s)	Guidance
III. Meetings between a Federal official(s) and a collection of individuals where advice is sought from the attendees on an individual basis are not subject to the Act.	102–3.40(e)	1. May an agency official meet with a number of persons collectively to obtain their individual views without violating the Act? 2. Does the concept of an ''individual'' apply only to ''natural persons?''	A. The answer to questions 1 and 2 is yes. The Act applies only where a group is established or utilized to provide advice or recommendations ''as a group.'' (i) A mere assemblage or collection of individuals where the attendees are providing individual advice is not acting ''as a group'' under the Act. (ii) In this respect, ''individual'' is not limited to ''natural persons.'' Where the group consists of representatives of various existing organizations, each representative individually may provide advice on behalf of that person's organization without violating the Act, if those organizations themselves are not ''managed or controlled'' by the agency.
IV. Meetings between Federal, State, local, and tribal elected officials are not subject to the Act.	102–3.40(g)	1. Is the exclusion from the Act covering elected officials of State, local, and tribal governments acting in their official capacities also applicable to associations of State officials?	A. Yes. The scope of activities covered by the exclusion from the Act for intergovernmental activities should be construed broadly to facilitateFederal/State/local/tribal discussions on shared intergovernmental program responsibilities or administration. Pursuant to a Presidential delegation, the Office of Management and Budget (OMB) issued guidelines for this exemption, authorized by section 204(b) of the Unfunded Mandates Reform Act of 1995, 2U.S.C. 1534(b). (See OMB Memorandum M–95–20, dated September 21, 1995, published at 60 FR 50651 (September 29, 1995), and which is available from the Committee Management Secretariat (MC), General Services Administration, 1800 F Street, NW, Washington, DC 20405–0002).
V. Advisory committees established under the Act may perform advisory functions only, unless authorized to perform ''operational'' duties by the Congress or by Presidential directive.	102–3.30(e), 102–3.40(k)	1. Are ''operational committees'' subject to the Act, even if they may engage in some advisory activities?	A. No, so long as the operational functions performed by the committee constitute the ''primary'' mission of the committee. Only committees established or utilized by the executive branch in the interest of obtaining advice or recommendations are subject to the Act. However, without specific authorization by the Congress or direction by the President, Federal functions (decisionmaking or operations) cannot be delegated to, or assumed by, non-Federal individuals or entities.

APPENDIX A TO SUBPART A—Continued

Key points and principles	Section(s)	Question(s)	Guidance
VI. Committees authorized by the Congress in law or by Presidential directive to perform primarily ''operational'' functions are not subject to the Act.	102–3.40(k)	1. What characteristics are common to ''operational committees?'' 2. A committee created by the Congress by statute is responsible, for example, for developing plans and events to commemorate the contributions of wildlife to the enjoyment of the Nation's parks. Part of the committee's role includes providing advice to certain Federal agencies as may be necessary to coordinate these events. Is this committee subject to FACA?	A. In answer to question 1, non-advisory, or ''operational'' committees generally have the following characteristics: (i) Specific functions and/or authorities provided by the Congress in law or by Presidential directive; (ii) The ability to make and implement traditionally Governmental decisions; and (iii) The authority to perform specific tasks to implement a Federal program. B. Agencies are responsible for determining whether or not a committee primarily provides advice or recommendations and is, therefore, subject to the Act, or is primarily ''operational'' and not covered by FACA. C. The answer to question 2 is no. The committee is not subject to the Act because: (i) Its functions are to plan and implement specific tasks; (ii) The committee has been granted the express authority by the Congress to perform its statutorily required functions; and (iii) Its incidental role of providing advice to other Federal agencies is secondary to its primarily operational role of planning and implementing specific tasks and performing statutory functions.

Subpart B—How Are Advisory Committees Established, Renewed, Reestablished, and Terminated?

§ 102–3.45 What does this subpart cover and how does it apply?

Requirements for establishing and terminating advisory committees vary depending on the establishing entity and the source of authority for the advisory committee. This subpart covers the procedures associated with the establishment, renewal, reestablishment, and termination of advisory committees. These procedures include consulting with the Secretariat, preparing and filing an advisory committee charter, publishing notice in the **Federal Register**, and amending an advisory committee charter.

§ 102–3.50 What are the authorities for establishing advisory committees?

FACA identifies four sources of authority for establishing an advisory committee:

(a) *Required by statute.* By law where the Congress establishes an advisory committee, or specifically directs the President or an agency to establish it (*non-discretionary*);

(b) *Presidential authority.* By Executive order of the President or other Presidential directive (*non-discretionary*);

(c) *Authorized by statute.* By law where the Congress authorizes, but does not direct the President or an agency to establish it (*discretionary*); or

(d) *Agency authority.* By an agency under general authority in title 5 of the United States Code or under other general agency-authorizing statutes (*discretionary*).

§ 102–3.55 What rules apply to the duration of an advisory committee?

(a) An advisory committee automatically terminates two years after its date of establishment unless:

(1) The statutory authority used to establish the advisory committee provides a different duration;

(2) The President or agency head determines that the advisory committee has fulfilled the purpose for which it was established and terminates the advisory committee earlier;

(3) The President or agency head determines that the advisory committee is no longer carrying out the purpose for which it was established and terminates the advisory committee earlier; or

(4) The President or agency head renews the committee not later than two years after its date of establishment in accordance with § 102–3.60. If an advisory committee needed by the President or an agency terminates because it was not renewed in a timely manner, or if the advisory committee has been terminated under the provisions of § 102–3.30(b), it can be reestablished in accordance with § 102–3.60.

(b) When an advisory committee terminates, the agency shall notify the Secretariat of the effective date of the termination.

§ 102–3.60 What procedures are required to establish, renew, or reestablish a discretionary advisory committee?

(a) *Consult with the Secretariat.* Before establishing, renewing, or reestablishing a discretionary advisory committee and filing the charter as addressed later in § 102–3.70, the agency head must consult with the Secretariat. As part of this consultation, agency heads are encouraged to engage in constructive dialogue with the Secretariat. With a full understanding of the background and purpose behind the proposed advisory committee, the Secretariat may share its knowledge and experience with the agency on how best to make use of the proposed advisory committee, suggest alternate methods of attaining its purpose that the agency may wish to consider, or inform the agency of a pre-existing advisory committee performing similar functions.

(b) *Include required information in the consultation.* Consultations covering the establishment, renewal, and reestablishment of advisory committees must, as a minimum, contain the following information:

(1) *Explanation of need.* An explanation stating why the advisory committee is essential to the conduct of agency business and in the public interest;

(2) *Lack of duplication of resources.* An explanation stating why the advisory committee's functions cannot be performed by the agency, another existing committee, or other means such as a public hearing; and

(3) *Fairly balanced membership.* A description of the agency's plan to attain fairly balanced membership. The plan will ensure that, in the selection of members for the advisory committee, the agency will consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the advisory committee. Advisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed.

§ 102–3.65 What are the public notification requirements for discretionary advisory committees?

A notice to the public in the **Federal Register** is required when a discretionary advisory committee is established, renewed, or reestablished.

(a) *Procedure.* Upon receiving notice from the Secretariat that its review is complete in accordance with § 102–3.60(a), the agency must publish a notice in the **Federal Register** announcing that the advisory committee is being established, renewed, or reestablished. For the establishment of a new advisory committee, the notice also must describe the nature and purpose of the advisory committee and affirm that the advisory committee is necessary and in the public interest.

(b) *Time required for notices.* Notices of establishment and reestablishment of advisory committees must appear at least 15 calendar days before the charter is filed, except that the Secretariat may approve less than 15 calendar days when requested by the agency for good cause. This requirement for advance notice does not apply to advisory committee renewals, notices of which may be published concurrently with the filing of the charter.

§ 102–3.70 What are the charter filing requirements?

No advisory committee may meet or take any action until a charter has been filed by the Committee Management Officer (CMO) designated in accordance with section 8(b) of the Act, or by another agency official designated by the agency head.

(a) *Requirement for discretionary advisory committees.* To establish, renew, or reestablish a discretionary advisory committee, a charter must be filed with:

(1) The agency head;

(2) The standing committees of the Senate and the House of Representatives having legislative jurisdiction of the agency, the date of filing with which constitutes the official date of establishment for the advisory committee;

(3) The Library of Congress, Anglo-American Acquisitions Division, Government Documents Section, Federal Advisory Committee Desk, 101 Independence Avenue, SE., Washington, DC 20540–4172; and

(4) The Secretariat, indicating the date the charter was filed in accordance with paragraph (a)(2) of this section.

(b) *Requirement for non-discretionary advisory committees.* Charter filing requirements for non-discretionary advisory committees are the same as those in paragraph (a) of this section, except the date of establishment for a Presidential advisory committee is the date the charter is filed with the Secretariat.

(c) *Requirement for subcommittees that report directly to the Government.* Subcommittees that report directly to a Federal officer or agency must comply with this subpart and include in a charter the information required by § 102–3.75.

§ 102–3.75 What information must be included in the charter of an advisory committee?

(a) *Purpose and contents of an advisory committee charter.* An advisory committee charter is intended to provide a description of an advisory committee's mission, goals, and objectives. It also provides a basis for evaluating an advisory committee's progress and effectiveness. The charter must contain the following information:

(1) The advisory committee's official designation;

(2) The objectives and the scope of the advisory committee's activity;

(3) The period of time necessary to carry out the advisory committee's purpose(s);

(4) The agency or Federal officer to whom the advisory committee reports;

(5) The agency responsible for providing the necessary support to the advisory committee;

(6) A description of the duties for which the advisory committee is responsible and specification of the authority for any non-advisory functions;

(7) The estimated annual costs to operate the advisory committee in dollars and person years;

(8) The estimated number and frequency of the advisory committee's meetings;

(9) The planned termination date, if less than two years from the date of establishment of the advisory committee;

(10) The name of the President's delegate, agency, or organization responsible for fulfilling the reporting requirements of section 6(b) of the Act, if appropriate; and

(11) The date the charter is filed in accordance with § 102–3.70.

(b) The provisions of paragraphs (a)(1) through (11) of this section apply to all subcommittees that report directly to a Federal officer or agency.

§ 102–3.80 How are minor charter amendments accomplished?

(a) *Responsibility and limitation.* The agency head is responsible for amending the charter of an advisory committee. Amendments may be either minor or major. The procedures for making changes and filing amended charters will depend upon the authority basis for the advisory committee. Amending any existing advisory committee charter does not constitute renewal of the advisory committee under § 102–3.60.

(b) *Procedures for minor amendments.* To make a minor amendment to an advisory committee charter, such as changing the name of the advisory committee or modifying the estimated number or frequency of meetings, the following procedures must be followed:

(1) *Non-discretionary advisory committees.* The agency head must ensure that any minor technical changes made to current charters are consistent with the relevant authority. When the Congress by law, or the President by Executive order, changes the authorizing language that has been the basis for establishing an advisory committee, the agency head or the chairperson of an independent Presidential advisory committee must amend those sections of the current charter affected by the new statute or Executive order, and file the amended charter as specified in § 102–3.70.

(2) *Discretionary advisory committees.* The charter of a discretionary advisory committee may be amended when an agency head determines that technical provisions of a filed charter are inaccurate, or specific provisions have changed or become obsolete with the passing of time, and that these amendments will not alter the advisory committee's objectives and scope

substantially. The agency must amend the charter language as necessary and file the amended charter as specified in § 102–3.70.

§ 102–3.85 How are major charter amendments accomplished?

Procedures for making major amendments to advisory committee charters, such as substantial changes in objectives and scope, duties, and estimated costs, are the same as in § 102–3.80, except that for discretionary advisory committees an agency must:

(a) Consult with the Secretariat on the amended language, and explain the purpose of the changes and why they are necessary; and

(b) File the amended charter as specified in § 102–3.70.

Appendix A to Subpart B of Part 102–3—Key Points and Principles

This appendix provides additional guidance in the form of answers to frequently asked questions and identifies key points and principles that may be applied to situations not covered elsewhere in this subpart. The guidance follows:

APPENDIX A TO SUBPART B

Key points and principles	Section(s)	Question(s)	Guidance
I. Agency heads must consult with the Secretariat prior to establishing a discretionary advisory committee.	102–3.60, 102–3.115	1. Can an agency head delegate to the Committee Management Officer (CMO) responsibility for consulting with the Secretariat regarding the establishment, renewal, or reestablishment of discretionary advisory committees?	A. Yes. Many administrative functions performed to implement the Act may be delegated. However, those functions related to approving the final establishment, renewal, or reestablishment of discretionary advisory committees are reserved for the agency head. Each agency CMO should assure that their internal processes for managing advisory committees include appropriate certifications by the agency head.
II. Agency heads are responsible for complying with the Act, including determining which discretionary advisory committees should be established and renewed.	102–3.60(a), 102–3.105	1. Who retains final authority for establishing or renewing a discretionary advisory committee?	A. Although agency heads retain final authority for establishing or renewing discretionary advisory committees, these decisions should be consistent with § 102–3.105(e) and reflect consultation with the Secretariat under § 102–3.60(a).
III. An advisory committee must be fairly balanced in its membership in terms of the points of view represented and the functions to be performed.	102–3.30(c), 102–3.60(b)(3) ..	1. What factors should be considered in achieving a ''balanced'' advisory committee membership?	A. The composition of an advisory committee's membership will depend upon several factors, including: (i) The advisory committee's mission; (ii) The geographic, ethnic, social, economic, or scientific impact of the advisory committee's recommendations; (iii) The types of specific perspectives required, for example, such as those of consumers, technical experts, the public at-large, academia, business, or other sectors; (iv) The need to obtain divergent points of view on the issues before the advisory committee; and (v) The relevance of State, local, or tribal governments to the development of the advisory committee's recommendations.
IV. Charters for advisory committees required by statute must be filed every two years regardless of the duration provided in the statute.	102–3.70(b)	1. If an advisory committee's duration exceeds two years, must a charter be filed with the Congress and GSA every two years?	A. Yes. Section 14(b)(2) of the Act provides that: Any advisory committee established by an Act of Congress shall file a charter upon the expiration of each successive two-year period following the date of enactment of the Act establishing such advisory committee.

Subpart C—How Are Advisory Committees Managed?

§ 102–3.90 What does this subpart cover and how does it apply?

This subpart outlines specific responsibilities and functions to be carried out by the General Services Administration (GSA), the agency head, the Committee Management Officer (CMO), and the Designated Federal Officer (DFO) under the Act.

§ 102–3.95 What principles apply to the management of advisory committees?

Agencies are encouraged to apply the following principles to the management of their advisory committees:

(a) *Provide adequate support.* Before establishing an advisory committee, agencies should identify requirements and assure that adequate resources are available to support anticipated activities. Considerations related to support include office space, necessary supplies and equipment, Federal staff support, and access to key decisionmakers.

(b) *Focus on mission.* Advisory committee members and staff should be fully aware of the advisory committee's mission, limitations, if any, on its duties, and the agency's goals and objectives. In general, the more specific an advisory committee's tasks and the more focused its activities are, the higher the likelihood will be that the advisory committee will fulfill its mission.

(c) *Follow plans and procedures*. Advisory committee members and their agency sponsors should work together to assure that a plan and necessary procedures covering implementation are in place to support an advisory committee's mission. In particular, agencies should be clear regarding what functions an advisory committee can perform legally and those that it cannot perform.

(d) *Practice openness*. In addition to achieving the minimum standards of public access established by the Act and this part, agencies should seek to be as inclusive as possible. For example, agencies may wish to explore the use of the Internet to post advisory committee information and seek broader input from the public.

(e) *Seek feedback*. Agencies continually should seek feedback from advisory committee members and the public regarding the effectiveness of the advisory committee's activities. At regular intervals, agencies should communicate to the members how their advice has affected agency programs and decisionmaking.

§ 102–3.100 What are the responsibilities and functions of GSA?

(a) Under section 7 of the Act, the General Services Administration (GSA) prepares regulations on Federal advisory committees to be prescribed by the Administrator of General Services, issues other administrative guidelines and management controls for advisory committees, and assists other agencies in implementing and interpreting the Act. Responsibility for these activities has been delegated by the Administrator to the GSA Committee Management Secretariat.

(b) The Secretariat carries out its responsibilities by:

(1) Conducting an annual comprehensive review of Governmentwide advisory committee accomplishments, costs, benefits, and other indicators to measure performance;

(2) Developing and distributing Governmentwide training regarding the Act and related statutes and principles;

(3) Supporting the Interagency Committee on Federal Advisory Committee Management in its efforts to improve compliance with the Act;

(4) Designing and maintaining a Governmentwide shared Internet-based system to facilitate collection and use of information required by the Act;

(5) Identifying performance measures that may be used to evaluate advisory committee accomplishments; and

(6) Providing recommendations for transmittal by the Administrator to the Congress and the President regarding proposals to improve accomplishment of the objectives of the Act.

§ 102–3.105 What are the responsibilities of an agency head?

The head of each agency that establishes or utilizes one or more advisory committees must:

(a) Comply with the Act and this Federal Advisory Committee Management part;

(b) Issue administrative guidelines and management controls that apply to all of the agency's advisory committees subject to the Act;

(c) Designate a Committee Management Officer (CMO);

(d) Provide a written determination stating the reasons for closing any advisory committee meeting to the public, in whole or in part, in accordance with the exemption(s) of the Government in the Sunshine Act, 5 U.S.C. 552b(c), as the basis for closure;

(e) Review, at least annually, the need to continue each existing advisory committee, consistent with the public interest and the purpose or functions of each advisory committee;

(f) Determine that rates of compensation for members (if they are paid for their services) and staff of, and experts and consultants to advisory committees are justified and that levels of agency support are adequate;

(g) Develop procedures to assure that the advice or recommendations of advisory committees will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;

(h) Assure that the interests and affiliations of advisory committee members are reviewed for conformance with applicable conflict of interest statutes, regulations issued by the U.S. Office of Government Ethics (OGE) including any supplemental agency requirements, and other Federal ethics rules;

(i) Designate a Designated Federal Officer (DFO) for each advisory committee and its subcommittees; and

(j) Provide the opportunity for reasonable participation by the public in advisory committee activities, subject to § 102–3.140 and the agency's guidelines.

§ 102–3.110 What are the responsibilities of a chairperson of an independent Presidential advisory committee?

The chairperson of an independent Presidential advisory committee must:

(a) Comply with the Act and this Federal Advisory Committee Management part;

(b) Consult with the Secretariat concerning the designation of a Committee Management Officer (CMO) and Designated Federal Officer (DFO); and

(c) Consult with the Secretariat in advance regarding any proposal to close any meeting in whole or in part.

§ 102–3.115 What are the responsibilities and functions of an agency Committee Management Officer (CMO)?

In addition to implementing the provisions of section 8(b) of the Act, the CMO will carry out all responsibilities delegated by the agency head. The CMO also should ensure that sections 10(b), 12(a), and 13 of the Act are implemented by the agency to provide for appropriate recordkeeping. Records to be kept by the CMO include, but are not limited to:

(a) *Charter and membership documentation*. A set of filed charters for each advisory committee and membership lists for each advisory committee and subcommittee;

(b) *Annual comprehensive review*. Copies of the information provided as the agency's portion of the annual comprehensive review of Federal advisory committees, prepared according to § 102–3.175(b);

(c) *Agency guidelines*. Agency guidelines maintained and updated on committee management operations and procedures; and

(d) *Closed meeting determinations*. Agency determinations to close or partially close advisory committee meetings required by § 102–3.105.

§ 102–3.120 What are the responsibilities and functions of a Designated Federal Officer (DFO)?

The agency head or, in the case of an independent Presidential advisory committee, the Secretariat, must designate a Federal officer or employee who must be either full-time or permanent part-time, to be the DFO for each advisory committee and its subcommittees, who must:

(a) Approve or call the meeting of the advisory committee or subcommittee;

(b) Approve the agenda, except that this requirement does not apply to a Presidential advisory committee;

(c) Attend the meetings;

(d) Adjourn any meeting when he or she determines it to be in the public interest; and

(e) Chair the meeting when so directed by the agency head.

§ 102–3.125 How should agencies consider the roles of advisory committee members and staff?

FACA does not assign any specific responsibilities to members of advisory

committees and staff, although both perform critical roles in achieving the goals and objectives assigned to advisory committees. Agency heads, Committee Management Officers (CMOs), and Designated Federal Officers (DFOs) should consider the distinctions between these roles and how they relate to each other in the development of agency guidelines implementing the Act and this Federal Advisory Committee Management part. In general, these guidelines should reflect:

(a) *Clear operating procedures.* Clear operating procedures should provide for the conduct of advisory committee meetings and other activities, and specify the relationship among the advisory committee members, the DFO, and advisory committee or agency staff;

(b) *Agency operating policies.* In addition to compliance with the Act, advisory committee members and staff may be required to adhere to additional agency operating policies; and

(c) *Other applicable statutes.* Other agency-specific statutes and regulations may affect the agency's advisory committees directly or indirectly. Agencies should ensure that advisory committee members and staff understand these requirements.

§ 102–3.130 What policies apply to the appointment, and compensation or reimbursement of advisory committee members, staff, and experts and consultants?

In developing guidelines to implement the Act and this Federal Advisory Committee Management part at the agency level, agency heads must address the following issues concerning advisory committee member and staff appointments, and considerations with respect to uniform fair rates of compensation for comparable services, or expense reimbursement of members, staff, and experts and consultants:

(a) *Appointment and terms of advisory committee members.* Unless otherwise provided by statute, Presidential directive, or other establishment authority, advisory committee members serve at the pleasure of the appointing or inviting authority. Membership terms are at the sole discretion of the appointing or inviting authority.

(b) *Compensation guidelines.* Each agency head must establish uniform compensation guidelines for members and staff of, and experts and consultants to an advisory committee.

(c) *Compensation of advisory committee members not required.* Nothing in this subpart requires an agency head to provide compensation to any member of an advisory committee, unless otherwise required by a specific statute.

(d) *Compensation of advisory committee members.* When an agency has authority to set pay administratively for advisory committee members, it may establish appropriate rates of pay (including any applicable locality pay authorized by the President's Pay Agent under 5 U.S.C. 5304(h)), not to exceed the rate for level IV of the Executive Schedule under 5 U.S.C. 5315, unless a higher rate expressly is allowed by another statute. However, the agency head personally must authorize a rate of basic pay in excess of the maximum rate of basic pay established for the General Schedule under 5 U.S.C. 5332, or alternative similar agency compensation system. This maximum rate includes any applicable locality payment under 5 U.S.C. 5304. The agency may pay advisory committee members on either an hourly or a daily rate basis. The agency may not provide additional compensation in any form, such as bonuses or premium pay.

(e) *Compensation of staff.* When an agency has authority to set pay administratively for advisory committee staff, it may establish appropriate rates of pay (including any applicable locality pay authorized by the President's Pay Agent under 5 U.S.C. 5304(h)), not to exceed the rate for level IV of the Executive Schedule under 5 U.S.C. 5315, unless a higher rate expressly is allowed by another statute. However, the agency head personally must authorize a rate of basic pay in excess of the maximum rate of basic pay established for the General Schedule under 5 U.S.C. 5332, or alternative similar agency compensation system. This maximum rate includes any applicable locality payment under 5 U.S.C. 5304. The agency must pay advisory committee staff on an hourly rate basis. The agency may provide additional compensation, such as bonuses or premium pay, so long as aggregate compensation paid in a calendar year does not exceed the rate for level IV of the Executive Schedule, with appropriate proration for a partial calendar year.

(f) *Other compensation considerations.* In establishing rates of pay for advisory committee members and staff, the agency must comply with any applicable statutes, Executive orders, regulations, or administrative guidelines. In determining an appropriate rate of basic pay for advisory committee members and staff, an agency must give consideration to the significance, scope, and technical complexity of the matters with which the advisory committee is concerned, and the qualifications required for the work involved. The agency also should take into account the rates of pay applicable to Federal employees who have duties that are similar in terms of difficulty and responsibility. An agency may establish rates of pay for advisory committee staff based on the pay these persons would receive if they were covered by the General Schedule in 5 U.S.C. Chapter 51 and Chapter 53, subchapter III, or by an alternative similar agency compensation system.

(g) *Compensation of experts and consultants.* Whether or not an agency has other authority to appoint and compensate advisory committee members or staff, it also may employ experts and consultants under 5 U.S.C. 3109 to perform work for an advisory committee. Compensation of experts and consultants may not exceed the maximum rate of basic pay established for the General Schedule under 5 U.S.C. 5332 (that is, the GS–15, step 10 rate, excluding locality pay or any other supplement), unless a higher rate expressly is allowed by another statute. The appointment and compensation of experts and consultants by an agency must be in conformance with applicable regulations issued by the U. S. Office of Personnel Management (OPM) (See 5 CFR part 304.).

(h) *Federal employees assigned to an advisory committee.* Any advisory committee member or staff person who is a Federal employee when assigned duties to an advisory committee remains covered during the assignment by the compensation system that currently applies to that employee, unless that person's current Federal appointment is terminated. Any staff person who is a Federal employee must serve with the knowledge of the Designated Federal Officer (DFO) for the advisory committee to which that person is assigned duties, and the approval of the employee's direct supervisor.

(i) *Other appointment considerations.* An individual who is appointed as an advisory committee member or staff person immediately following termination of another Federal appointment with a full-time work schedule may receive compensation at the rate applicable to the former appointment, if otherwise allowed by applicable law (without regard to the limitations on pay established in paragraphs (d) and (e) of this section). Any advisory committee staff person who is not a current Federal employee serving under an assignment must be appointed in accordance with applicable agency procedures, and in consultation with the DFO and the

members of the advisory committee involved.

(j) *Gratuitous services.* In the absence of any special limitations applicable to a specific agency, nothing in this subpart prevents an agency from accepting the gratuitous services of an advisory committee member or staff person who is not a Federal employee, or expert or consultant, who agrees in advance and in writing to serve without compensation.

(k) *Travel expenses.* Advisory committee members and staff, while engaged in the performance of their duties away from their homes or regular places of business, may be allowed reimbursement for travel expenses, including per diem in lieu of subsistence, as authorized by 5 U.S.C. 5703, for persons employed intermittently in the Government service.

(l) Services for advisory committee members with disabilities. While performing advisory committee duties, an advisory committee member with disabilities may be provided services by a personal assistant for employees with disabilities, if the member qualifies as an individual with disabilities as provided in section 501 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 791, and does not otherwise qualify for assistance under 5 U.S.C. 3102 by reason of being a Federal employee.

Appendix A to Subpart C of Part 102–3—Key Points and Principles

This appendix provides additional guidance in the form of answers to frequently asked questions and identifies key points and principles that may be applied to situations not covered elsewhere in this subpart. The guidance follows:

APPENDIX A TO SUBPART C

Key points and principles	Section	Question(s)	Guidance
I. FACA does not specify the manner in which advisory committee members and staff must be appointed.	102–3.105, 102–3.130(a)	1. Does the appointment of an advisory committee member necessarily result in a lengthy process?	A. No. Each agency head may specify those policies and procedures, consistent with the Act and this part, or other specific authorizing statute, governing the appointment of advisory committee members and staff. B. Some factors that affect how long the appointment process takes include: (i) Solicitation of nominations; (ii) Conflict of interest clearances; (iii) Security or background evaluations; (iv) Availability of candidates; and (v) Other statutory or administrative requirements. C. In addition, the extent to which agency heads have delegated responsibility for selecting members varies from agency to agency and may become an important factor in the time it takes to finalize the advisory committee's membership.
II. Agency heads retain the final authority for selecting advisory committee members, unless otherwise provided for by a specific statute or Presidential directive.	102–3.130(a)	1. Can an agency head select for membership on an advisory committee from among nominations submitted by an organization?	A. The answer to question 1 is yes. Organizations may propose for membership individuals to represent them on an advisory committee. However, the agency head establishing the advisory committee, or other appointing authority, retains the final authority for selecting all members.
		2. If so, can different persons represent the organization at different meetings?	B. The answer to question 2 also is yes. Alternates may represent an appointed member with the approval of the establishing agency, where the agency head is the appointing authority.
III. An agency may compensate advisory committee members and staff, and also employ experts and consultants.	102–3.130(d), 102–3.130(e), 102–3.130(g).	1. May members and staff be compensated for their service or duties on an advisory committee? 2. Are the guidelines the same for compensating both members and staff? 3. May experts and consultants be employed to perform other advisory committee work?	A. The answer to question 1 is yes. (i) However, FACA limits compensation for advisory committee members and staff to the rate for level IV of the Executive Schedule, unless higher rates expressly are allowed by other statutes. (ii) Although FACA provides for compensation guidelines, the Act does not require an agency to compensate its advisory committee members.

APPENDIX A TO SUBPART C—Continued

Key points and principles	Section	Question(s)	Guidance
			B. The answer to question 2 is no. The guidelines for compensating members and staff are similar, but not identical. For example, the differences are that: (i) An agency ''may'' pay members on either an hourly or a daily rate basis, and ''may not'' provide additional compensation in any form, such as bonuses or premium pay; while (ii) An agency ''must'' pay staff on an hourly rate basis only, and ''may'' provide additional compensation, so long as aggregate compensation paid in a calendar year does not exceed the rate for level IV of the Executive Schedule, with appropriate proration for a partial calendar year. C. The answer to question 3 is yes. Other work not part of the duties of advisory committee members or staff may be performed by experts and consultants. For additional guidance on the employment of experts and consultants, agencies should consult the applicable regulations issued by the U. S. Office of Personnel Management (OPM). (See 5 CFR part 304.)
IV. Agency heads are responsible for ensuring that the interests and affiliations of advisory committee members are reviewed for conformance with applicable conflict of interest statutes and other Federal ethics rules..	102–3.105(h)	1. Are all advisory committee members subject to conflict of interest statutes and other Federal ethics rules? 2. Who should be consulted for guidance on the proper application of Federal ethics rules to advisory committee members?	A. The answer to question 1 is no. Whether an advisory committee member is subject to Federal ethics rules is dependent on the member's status. The determination of a member's status on an advisory committee is largely a personnel classification matter for the appointing agency. Most advisory committee members will serve either as a ''representative'' or a ''special Government employee'' (SGE), based on the role the member will play. In general, SGEs are covered by regulations issued by the U. S. Office of Government Ethics (OGE) and certain conflict of interest statutes,while representatives are not subject to these ethics requirements. B. The answer to question 2 is the agency's Designated Agency Ethics Official (DAEO), who should be consulted prior to appointing members to an advisory committee in order to apply Federal ethics rules properly.
V. An agency head may delegate responsibility for appointing a Committee Management Officer (CMO) or Designated Federal Officer (DFO); however, there may be only one CMO for each agency..	102–3.105(c), 102–3.105(i)	1. Must an agency's CMO and each advisory committee DFO be appointed by the agency head?	A. The answer to question 1 is no. The agency head may delegate responsibility for appointing the CMO and DFOs. However, these appointments, including alternate selections, should be documented consistent with the agency's policies and procedures.

APPENDIX A TO SUBPART C—Continued

Key points and principles	Section	Question(s)	Guidance
		2. May an agency have more than one CMO?	B. The answer to question 2 also is no. The functions of the CMO are specified in the Act and include oversight responsibility for all advisory committees within the agency. Accordingly, only one CMO may be appointed to perform these functions. The agency may, however, create additional positions, including those in its subcomponents, which are subordinate to the CMO's agencywide responsibilities and functions.
VI. FACA is the principal statute pertaining to advisory committees. However, other statutes may impact their use and operations..	102–3.125(c)	1. Do other statutes or regulations affect the way an agency carries out its advisory committee management program?	A. Yes. While the Act provides a general framework for managing advisory committees Governmentwide, other factors may affect how advisory committees are managed. These include: (i) The statutory or Presidential authority used to establish an advisory committee; (ii) A statutory limitation placed on an agency regarding its annual expenditures for advisory committees; (iii) Presidential or agency management directives; (iv) The applicability of conflict of interest statutes and other Federal ethics rules; (v) Agency regulations affecting advisory committees; and (vi) Other requirements imposed by statute or regulation on an agency or its programs, such as those governing the employment of experts and consultants or the management of Federal records.

Subpart D—Advisory Committee Meeting and Recordkeeping Procedures

§ 102–3.135 What does this subpart cover and how does it apply?

This subpart establishes policies and procedures relating to meetings and other activities undertaken by advisory committees and their subcommittees. This subpart also outlines what records must be kept by Federal agencies and what other documentation, including advisory committee minutes and reports, must be prepared and made available to the public.

§ 102–3.140 What policies apply to advisory committee meetings?

The agency head, or the chairperson of an independent Presidential advisory committee, must ensure that:

(a) Each advisory committee meeting is held at a reasonable time and in a manner or place reasonably accessible to the public, to include facilities that are readily accessible to and usable by persons with disabilities, consistent with the goals of section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794;

(b) The meeting room or other forum selected is sufficient to accommodate advisory committee members, advisory committee or agency staff, and a reasonable number of interested members of the public;

(c) Any member of the public is permitted to file a written statement with the advisory committee;

(d) Any member of the public may speak to or otherwise address the advisory committee if the agency's guidelines so permit; and

(e) Any advisory committee meeting conducted in whole or part by a teleconference, videoconference, the Internet, or other electronic medium meets the requirements of this subpart.

§ 102–3.145 What policies apply to subcommittee meetings?

If a subcommittee makes recommendations directly to a Federal officer or agency, or if its recommendations will be adopted by the parent advisory committee without further deliberations by the parent advisory committee, then the subcommittee's meetings must be conducted in accordance with all openness requirements of this subpart.

§ 102–3.150 How are advisory committee meetings announced to the public?

(a) A notice in the **Federal Register** must be published at least 15 calendar days prior to an advisory committee meeting, which includes:

(1) The name of the advisory committee (or subcommittee, if applicable);

(2) The time, date, place, and purpose of the meeting;

(3) A summary of the agenda, and/or topics to be discussed;

(4) A statement whether all or part of the meeting is open to the public or closed; if the meeting is closed state the reasons why, citing the specific exemption(s) of the Government in the Sunshine Act, 5 U.S.C. 552b(c), as the basis for closure; and

(5) The name and telephone number of the Designated Federal Officer (DFO) or other responsible agency official who may be contacted for additional information concerning the meeting.

(b) In exceptional circumstances, the agency or an independent Presidential advisory committee may give less than 15 calendar days notice, provided that the reasons for doing so are included in the advisory committee meeting notice published in the **Federal Register**.

§ 102–3.155 How are advisory committee meetings closed to the public?

To close all or part of an advisory committee meeting, the Designated Federal Officer (DFO) must:

(a) *Obtain prior approval.* Submit a request to the agency head, or in the case of an independent Presidential

advisory committee, the Secretariat, citing the specific exemption(s) of the Government in the Sunshine Act, 5 U.S.C. 552b(c), that justify the closure. The request must provide the agency head or the Secretariat sufficient time (generally, 30 calendar days) to review the matter in order to make a determination before publication of the meeting notice required by § 102–3.150.

(b) *Seek General Counsel review.* The General Counsel of the agency or, in the case of an independent Presidential advisory committee, the General Counsel of GSA should review all requests to close meetings.

(c) *Obtain agency determination.* If the agency head, or in the case of an independent Presidential advisory committee, the Secretariat, finds that the request is consistent with the provisions in the Government in the Sunshine Act and FACA, the appropriate agency official must issue a determination that all or part of the meeting be closed.

(d) *Assure public access to determination.* The agency head or the chairperson of an independent Presidential advisory committee must make a copy of the determination available to the public upon request.

§ 102–3.160 What activities of an advisory committee are not subject to the notice and open meeting requirements of the Act?

The following activities of an advisory committee are excluded from the procedural requirements contained in this subpart:

(a) *Preparatory work.* Meetings of two or more advisory committee or subcommittee members convened solely to gather information, conduct research, or analyze relevant issues and facts in preparation for a meeting of the advisory committee, or to draft position papers for deliberation by the advisory committee; and

(b) *Administrative work.* Meetings of two or more advisory committee or subcommittee members convened solely to discuss administrative matters of the advisory committee or to receive administrative information from a Federal officer or agency.

§ 102–3.165 How are advisory committee meetings documented?

(a) The agency head or, in the case of an independent Presidential advisory committee, the chairperson must ensure that detailed minutes of each advisory committee meeting, including one that is closed or partially closed to the public, are kept. The chairperson of each advisory committee must certify the accuracy of all minutes of advisory committee meetings.

(b) The minutes must include:

(1) The time, date, and place of the advisory committee meeting;

(2) A list of the persons who were present at the meeting, including advisory committee members and staff, agency employees, and members of the public who presented oral or written statements;

(3) An accurate description of each matter discussed and the resolution, if any, made by the advisory committee regarding such matter; and

(4) Copies of each report or other document received, issued, or approved by the advisory committee at the meeting.

(c) The Designated Federal Officer (DFO) must ensure that minutes are certified within 90 calendar days of the meeting to which they relate.

§ 102–3.170 How does an interested party obtain access to advisory committee records?

Timely access to advisory committee records is an important element of the public access requirements of the Act. Section 10(b) of the Act provides for the contemporaneous availability of advisory committee records that, when taken in conjunction with the ability to attend committee meetings, provide a meaningful opportunity to comprehend fully the work undertaken by the advisory committee. Although advisory committee records may be withheld under the provisions of the Freedom of Information Act (FOIA), as amended, if there is a *reasonable expectation* that the records sought fall within the exemptions contained in section 552(b) of FOIA, agencies may not require members of the public or other interested parties to file requests for non-exempt advisory committee records under the request and review process established by section 552(a)(3) of FOIA.

§ 102–3.175 What are the reporting and recordkeeping requirements for an advisory committee?

(a) *Presidential advisory committee follow-up report.* Within one year after a Presidential advisory committee has submitted a public report to the President, a follow-up report required by section 6(b) of the Act must be prepared and transmitted to the Congress detailing the disposition of the advisory committee's recommendations. The Secretariat shall assure that these reports are prepared and transmitted to the Congress as directed by the President, either by the President's delegate, by the agency responsible for providing support to a Presidential advisory committee, or by the responsible agency or organization designated in the charter of the Presidential advisory committee pursuant to § 102–3.75(a)(10). In performing this function, GSA may solicit the assistance of the President's delegate, the Office of Management and Budget (OMB), or the responsible agency Committee Management Officer (CMO), as appropriate. Reports shall be consistent with specific guidance provided periodically by the Secretariat.

(b) *Annual comprehensive review of Federal advisory committees.* To conduct an annual comprehensive review of each advisory committee as specified in section 7(b) of the Act, GSA requires Federal agencies to report information on each advisory committee for which a charter has been filed in accordance with § 102–3.70, and which is in existence during any part of a Federal fiscal year. Committee Management Officers (CMOs), Designated Federal Officers (DFOs), and other responsible agency officials will provide this information by data filed electronically with GSA on a fiscal year basis, using a Governmentwide shared Internet-based system that GSA maintains. This information shall be consistent with specific guidance provided periodically by the Secretariat. The preparation of these electronic submissions by agencies has been assigned interagency report control number (IRCN) 0304–GSA–AN.

(c) *Annual report of closed or partially-closed meetings.* In accordance with section 10(d) of the Act, advisory committees holding closed or partially-closed meetings must issue reports at least annually, setting forth a summary of activities and such related matters as would be informative to the public consistent with the policy of 5 U.S.C. 552(b).

(d) *Advisory committee reports.* Subject to 5 U.S.C. 552, 8 copies of each report made by an advisory committee, including any report of closed or partially-closed meetings as specified in paragraph (c) of this section and, where appropriate, background papers prepared by experts or consultants, must be filed with the Library of Congress as required by section 13 of the Act for public inspection and use at the location specified § 102–3.70(a)(3).

(e) *Advisory committee records.* Official records generated by or for an advisory committee must be retained for the duration of the advisory committee. Upon termination of the advisory committee, the records must be processed in accordance with the Federal Records Act (FRA), 44 U.S.C. Chapters 21, 29–33, and regulations issued by the National Archives and Records Administration (NARA) (see 36 CFR parts 1220, 1222, 1228, and 1234),

or in accordance with the Presidential Records Act (PRA), 44 U.S.C. Chapter 22.

Appendix A to Subpart D of Part 102–3—Key Points and Principles

This appendix provides additional guidance in the form of answers to frequently asked questions and identifies key points and principles that may be applied to situations not covered elsewhere in this subpart. The guidance follows:

APPENDIX A TO SUBPART D

Key points and principles	Section(s)	Question(s)	Guidance
I. With some exceptions, advisory committee meetings are open to the public.	102–3.140, 102–3.145(a), 102–3.155.	1. Must all advisory committee and subcommittee meetings be open to the public?	A. No. Advisory committee meetings may be closed when appropriate, in accordance with the exemption(s) for closure contained in the Government in the Sunshine Act, 5 U.S.C. 552b(c). (i) Subcommittees that report to a parent advisory committee, and not directly to a Federal officer or agency, are not required to open their meetings to the public or comply with the procedures in the Act for announcing meetings. (ii) However, agencies are cautioned to avoid excluding the public from attending any meeting where a subcommittee develops advice or recommendations that are not expected to be reviewed and considered by the parent advisory committee before being submitted to a Federal officer or agency. These exclusions may run counter to the provisions of the Act requiring contemporaneous access to the advisory committee deliberative process.
II. Notices must be published in the **Federal Register** announcing advisory committee meetings.	102–3.150	1. Can agencies publish a single **Federal Register** notice announcing multiple advisory committee meetings?	A. Yes, agencies may publish a single notice announcing multiple meetings so long as these notices contain all of the information required by § 102–3.150. (i) ''Blanket notices'' should not announce meetings so far in advance as to prevent the public from adequately being informed of an advisory committee's schedule. (ii) An agency's Office of General Counsel should be consulted where these notices include meetings that are either closed or partially closed to the public.

APPENDIX A TO SUBPART D—Continued

Key points and principles	Section(s)	Question(s)	Guidance
III. Although certain advisory committee records may be withheld under the Freedom of Information Act (FOIA), as amended, 5 U.S.C. 552, agencies may not require the use of FOIA procedures for records available under section 10(b) of FACA.	102–3.170	1. May an agency require the use of its internal FOIA procedures for access to advisory committee records that are not exempt from release under FOIA?	A. No. Section 10(b) of FACA provides that: Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist. (i) The purpose of section 10(b) of the Act is to provide for the contemporaneous availability of advisory committee records that, when taken in conjunction with the ability to attend advisory committee meetings, provide a meaningful opportunity to comprehend fully the work undertaken by the advisory committee. (ii) Although advisory committee records may be withheld under the provisions of FOIA if there is a reasonable expectation that the records sought fall within the exemptions contained in section 552(b) of FOIA, agencies may not require members of the public or other interested parties to file requests for nonexempt advisory committee records under the request and review process established by section 552(a)(3) of FOIA. (iii) Records covered by the exemptions set forth in section 552(b) of FOIA may be withheld. An opinion of the Office of Legal Counsel (OLC), U.S. Department of Justice concludes that: FACA requires disclosure of written advisory committee documents, including predecisional materials such as drafts, working papers, and studies. The disclosure exemption available to agencies under exemption 5 of FOIA for predecisional documents and other privileged materials is narrowly limited in the context of FACA to privileged ''inter-agency or intra-agency'' documents prepared by an agency and transmitted to an advisory committee. The language of the FACA statute and its legislative history support this restrictive application of exemption 5 to requests for public access to advisory committee documents. Moreover, since an advisory committee is not itself an agency, this construction is supported by the express language of exemption 5 which applies only to inter-agency or intra-agency materials. (iv) Agencies first should determine, however, whether or not records being sought by the public fall within the scope of FACA in general, and section 10(b) of the Act in particular, prior to applying the available exemptions under FOIA. (See OLC Opinion 12 Op. O.L.C. 73, dated April 29, 1988, which is available from the Committee Management Secretariat (MC), General Services Administration, 1800 F Street, NW., Washington, DC 20405–0002.)

APPENDIX A TO SUBPART D—Continued

Key points and principles	Section(s)	Question(s)	Guidance
IV. Advisory committee records must be managed in accordance with the Federal Records Act (FRA), 44 U.S.C. Chapters 21, 29–33, and regulations issued by the National Archives and Records Administration (NARA) (see 36 CFR parts 1220, 1222, 1228, and 1234), or the Presidential Records Act (PRA), 44 U.S.C. Chapter 22.	102–175(e)	1. How must advisory committee records be treated and preserved?	A. In order to ensure proper records management, the Committee Management Officer (CMO), Designated Federal Officer (DFO), or other representative of the advisory committee, in coordination with the agency's Records Management Officer, should clarify upon the establishment of the advisory committee whether its records will be managed in accordance with the FRA or the PRA. B. Official records generated by or for an advisory committee must be retained for the duration of the advisory committee. Responsible agency officials are encouraged to contact their agency's Records Management Officer or NARA as soon as possible after the establishment of the advisory committee to receive guidance on how to establish effective records management practices. Upon termination of the advisory committee, the records must be processed in accordance with the FRA and regulations issued by NARA, or in accordance with the PRA. C. The CMO, DFO, or other representative of an advisory committee governed by the FRA, in coordination with the agency's Records Management Officer, must contact NARA in sufficient time to review the process for submitting any necessary disposition schedules of the advisory committee's records upon termination. In order to ensure the proper disposition of the advisory committee's records, disposition schedules need to be submitted to NARA no later than 6 months before the termination of the advisory committee. D. For Presidential advisory committees governed by the PRA, the CMO, DFO, or other representative of the advisory committee should consult with the White House Counsel on the preservation of any records subject to the PRA, and may also confer with NARA officials.

Subpart E—How Does This Subpart Apply to Advice or Recommendations Provided to Agencies by the National Academy of Sciences or the National Academy of Public Administration?

§ 102–3.180 What does this subpart cover and how does it apply?

This subpart provides guidance to agencies on compliance with section 15 of the Act. Section 15 establishes requirements that apply only in connection with a funding or other written agreement involving an agency's use of advice or recommendations provided to the agency by the National Academy of Sciences (NAS) or the National Academy of Public Administration (NAPA), if such advice or recommendations were developed by use of a committee created by either academy. For purposes of this subpart, NAS also includes the National Academy of Engineering, the Institute of Medicine, and the National Research Council. Except with respect to NAS committees that were the subject of judicial actions filed before December 17, 1997, no part of the Act other than section 15 applies to any committee created by NAS or NAPA.

§ 102–3.185 What does this subpart require agencies to do?

(a) *Section 15 requirements.* An agency may not use any advice or recommendation provided to an agency by the National Academy of Sciences (NAS) or the National Academy of Public Administration (NAPA) under an agreement between the agency and an academy, if such advice or recommendation was developed by use of a committee created by either academy, unless:

(1) The committee was not subject to any actual management or control by an agency or officer of the Federal Government; and

(2) In the case of NAS, the academy certifies that it has complied substantially with the requirements of section 15(b) of the Act; or

(3) In the case of NAPA, the academy certifies that it has complied substantially with the requirements of sections 15(b) (1), (2), and (5) of the Act.

(b) *No agency management or control.* Agencies must not manage or control the specific procedures adopted by each academy to comply with the requirements of section 15 of the Act that are applicable to that academy. In addition, however, any committee created and used by an academy in the development of any advice or recommendation to be provided by the

academy to an agency must be subject to both actual management and control by that academy and not by the agency.

(c) *Funding agreements.* Agencies may enter into contracts, grants, and cooperative agreements with NAS or NAPA that are consistent with the requirements of this subpart to obtain advice or recommendations from such academy. These funding agreements require, and agencies may rely upon, a written certification by an authorized representative of the academy provided to the agency upon delivery to the agency of each report containing advice or recommendations required under the agreement that:

(1) The academy has adopted policies and procedures that comply with the applicable requirements of section 15 of the Act; and

(2) To the best of the authorized representative's knowledge and belief, these policies and procedures substantially have been complied with in performing the work required under the agreement.

Appendix A to Subpart E of Part 102–3—Key Points and Principles

This appendix provides additional guidance in the form of answers to frequently asked questions and identifies key points and principles that may be applied to situations not covered elsewhere in this subpart. The guidance follows:

APPENDIX A TO SUBPART E

Key points and principles	Section(s)	Question(s)	Guidance
I. Section 15 of the Act allows the National Academy of Sciences (NAS) and the National Academy of Public Administration (NAPA) to adopt separate procedures for complying with FACA.	102–3.185(a)	1. May agencies rely upon an academy certification regarding compliance with section 15 of the Act if different policies and procedures are adopted by NAS and NAPA?	A. Yes. NAS and NAPA are completely separate organizations. Each is independently chartered by the Congress for different purposes, and Congress has recognized that the two organizations are structured and operate differently. Agencies should defer to the discretion of each academy to adopt policies and procedures that will enable it to comply substantially with the provisions of section 15 of the Act that apply to that academy.
II. Section 15 of the Act allows agencies to enter into funding agreements with NAS and NAPA without the academies' committees being ''managed'' or ''controlled''.	102–3.185(c)	1. Can an agency enter into a funding agreement with an academy which provides for the preparation of one or more academy reports containing advice or recommendations to the agency, to be developed by the academy by use of a committee created by the academy, without subjecting an academy to ''actual management or control'' by the agency?	A. Yes, if the members of the committee are selected by the academy and if the committee's meetings, deliberations, and the preparation of reports are all controlled by the academy. Under these circumstances, neither the existence of the funding agreement nor the fact that it contemplates use by the academy of an academy committee would constitute actual management or control of the committee by the agency.

[FR Doc. 01–17350 Filed 7–18–01; 8:45 am]

BILLING CODE 6820–34–U

Federal Register

Thursday,
July 19, 2001

Part III

Environmental Protection Agency

40 CFR Part 82

Protection of Stratospheric Ozone: Process for Exempting Quarantine and Preshipment Applications of Methyl Bromide; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–7014–5]

RIN 2060–A142

Protection of Stratospheric Ozone: Process for Exempting Quarantine and Preshipment Applications of Methyl Bromide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule.

SUMMARY: With this rulemaking, EPA is taking interim final action to amend the accelerated phaseout regulations that govern the production, import, export, transformation and destruction of substances that deplete the ozone layer under the authority of Title VI of the Clean Air Act Amendments of 1990 (CAA or the Act). Today's amendments incorporate an exemption permitted under the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) and required by recent changes in Title VI of the CAA. Specifically, EPA is creating a temporary exemption, through December 31, 2002, from the consumption and production phaseout for quantities of Class I, Group VI controlled substances (methyl bromide) that are used for quarantine and preshipment. Following public comment, EPA intends to issue a final action to extend this exemption beyond December 31, 2002. EPA is also actively pursuing a separate notice and comment rulemaking, with stakeholder involvement, to establish methyl bromide exemptions for critical uses and emergency uses beyond the phaseout of production and import on January 1, 2005.

DATES: This rule is effective July 19, 2001 and the additions to 40 CFR Part 82 will remain in effect through December 31, 2002. The provisions and requirements established in today's rule apply to the entire 2001 and 2002 calendar years (control periods). EPA will consider all written comments received by October 12, 2001 to determine whether any changes are necessary prior to issuing a final action to extend this exemption beyond December 31, 2002.

ADDRESSES: Should you have comments that are directly related to this rulemaking please submit them in duplicate (two copies) to: Air Docket No. A–2000–24, U.S. Environmental Protection Agency, Mail Code 6102, 1200 Pennsylvania Ave., NW., Washington, DC, 20460. In addition, should you have comments that are separately related to a different issue than those raised by this rulemaking you may send them directly to U.S. Environmental Protection Agency, Global Programs Division (6205J), 1200 Pennsylvania Ave., NW., Washington, DC 20460.

Materials relevant to this rulemaking are contained in Docket No. A–2000–24. The Docket is located in room M–1500, First Floor, Waterside Mall at 401 M Street, SW., Washington, DC 20460. The materials may be inspected from 8:30 am until 5:30 pm Monday through Friday. A reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Tom Land, U.S. Environmental Protection Agency, Global Programs Division (6205J), 1200 Pennsylvania Ave., NW., Washington, DC, 20460, 202–564–9185.

SUPPLEMENTARY INFORMATION: EPA is taking this action as an interim final rule without prior proposal and public comment because EPA finds that the good cause exemption from the notice-and-comment rulemaking requirement of the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, applies here. Section 307(d) of the Clean Air Act (CAA) states that in the case of any rule to which section 307(d) applies, notice of proposed rulemaking must be published in the **Federal Register** (CAA307(d)(3)). The promulgation or revision of regulations under title VI of the CAA is generally subject to section 307(d). However, section 307(d) does not apply to any rule referred to in subparagraphs (A) or (B) of section 553(b) of the APA. Section 553(b)(B) of the APA, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and comment 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 comment.

EPA has determined that there is good cause for making today's rule an interim final rule without prior proposal and opportunity for comment because we view these revisions as protecting commodity trade from the adverse impacts of quarantine pest infestations, as well as protecting the supply of imported fruits and vegetables available to the general public. Without the creation of the exemption by this rule, quantities of methyl bromide used for quarantine and preshipment would be counted against the production and consumption allowances already limited by prior rulemaking (65 FR 70795), which for 2001 constitute 50% of the baseline. Having to compete for non-exempt methyl bromide, without today's exemption, fumigators at U.S. ports might not be able to meet U.S. requirements to treat imported commodities (under the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) requirements). This could jeopardize the supplies of these commodities for U.S. consumers because in the absence of required treatments ships would be turned away. Alternatively, the absence of today's exemption could increase the risk of an outbreak of a quarantine pest within the United States because shipments are typically unloaded onto the docks in preparation for fumigation with methyl bromide. Unloading containers at the docks could occur prior to a realization that methyl bromide is unavailable at the port and thereby jeopardize U.S. commodities with a quarantine pest infestation. If an infestation of a quarantine pest occurs, the amount of methyl bromide used could greatly increase. For example, when the port of Houston was infested with the Mediterranean snail, a fumigator who typically uses 40,000–50,000 pounds a year, used 21,000 pounds in 7½ weeks to treat this outbreak of a quarantine pest. In addition, exporters might not be able to ship U.S. commodities overseas because they would not be able to meet foreign import requirements without today's exemption. Thus, notice and public procedure are impracticable and contrary to the public interest. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B). Nonetheless, EPA is providing 90 days for submission of public comments following today's action. EPA will consider all written comments submitted in the allotted time period to determine if any change is warranted prior to taking final action that would extend this exemption beyond December 31, 2002. The phaseout program operates in control periods that correspond to calendar years. EPA believes that the exemption should correspond to whole control periods, i.e., entire calendar years. EPA does not believe it will be possible to take final action before the end of the 2001 control period. Because the Agency is providing a 90-day comment period and wants to ensure there is sufficient time to carefully review comments and consider other approaches, and to simplify the administrative implementation for affected entities, today's exemption is effective through December 31, 2002.

Section 553(d) of the APA generally provides that rules may not take effect

earlier than 30 days after they are published in the **Federal Register**. However, APA section 553(d) excepts from this provision any action that grants or recognizes an exemption or relieves a restriction. Since today's action grants an exemption from the phaseout of production and import of methyl bromide, EPA is making this action effective immediately to ensure the availability of methyl bromide for quarantine and preshipment through December 31, 2002.

EPA emphasizes that this rule is intended only to address the basic implementation of the methyl bromide quarantine and preshipment exemptions according to the definitions agreed upon by the Montreal Protocol Parties. Any deviations from the Protocol Parties' definitions are constrained by the Protocol and the Clean Air Act, and therefore are not addressed in today's rulemaking.

Table of Contents

I. What is the Background of the Phaseout Regulations for Ozone-Depleting Substances?
II. What is Methyl Bromide?
III. What are Examples of Quarantine and Preshipment Uses of Methyl Bromide?
IV. What is the Legal Authority for Exempting the Production and Import of Methyl Bromide for Use in Quarantine and Preshipment Applications?
V. What is the Definition of Quarantine and Preshipment Applications?
A. Are there clarifications of the definitions regarding trade within the U.S.?
B. Are there additional qualifiers associated with the definition of preshipment applications?
C. Are there additional qualifiers associated with the definition of quarantine applications?
D. How do the definitions of quarantine and preshipment applications apply to food sanitation?
E. How do these definitions apply to "propagative material"?
F. How do these definitions apply to in-transit applications?
VI. What is the Process for Exempting Methyl Bromide for Use in Quarantine and Preshipment Applications?
A. Are Producer and Importer Quarterly Reports and Recordkeeping Changing?
B. Are Methyl Bromide Applicators Required to Report?
C. Are Distributors Required to Report?
D. What about Methyl Bromide Exported for Quarantine and Preshipment Applications?
E. Will there be a FIFRA Pesticide Label Change?
VII. What are Other Considerations on which EPA is Seeking Comment?
A. What are considerations on which the Agency is seeking comment regarding definitions under the International Plant Protection Convention (IPPC)?
B. What are considerations on which the Agency is seeking comment regarding prophylactic fumigation of U.S. exports when the fumigation is not mandated by import regulations?
C. What are considerations on which the Agency is seeking comment regarding the exclusion of specific quarantine and preshipment applications from the exemption at some future time?
D. What are considerations on which the Agency is seeking comment regarding national security fumigations?
VIII. What are the Steps to Conform the U.S. Methyl Bromide Phaseout Schedule and Exemptions to the Montreal Protocol and Amended Clean Air Act?
IX. Administrative Requirements
X. Congressional Review

Entities potentially regulated by this action are those associated with methyl bromide that is used for quarantine and preshipment applications. In addition, this action potentially regulates entities importing and exporting methyl bromide. Potentially regulated categories and entities include:

Category	Examples of regulated entities
Industry	Producers, Importers and Exporters of methyl bromide. Distributors of methyl bromide used for quarantine and preshipment. Applicators of methyl bromide used for quarantine and preshipment. Commodity Owners or Shippers of Goods that request the quarantine or preshipment application of methyl bromide in accordance with treatments, official controls or requirements.

Table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility, company, business, organization, etc. is regulated by this action, you should carefully examine the regulations promulgated at 40 CFR 82, Subpart A. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

I. What Is the Background of the Phaseout Regulations for Ozone-Depleting Substances?

The current regulatory requirements of the Stratospheric Ozone Protection Program that limit production and consumption of ozone-depleting substances were promulgated by the Environmental Protection Agency (EPA or the Agency) in the **Federal Register** on December 20, 1994 (59 FR 65478), May 10, 1995 (60 FR 24970), August 4, 1998 (63 FR 41625), and October 5, 1998 (63 FR 53290). The regulatory program was originally published in the **Federal Register** on August 12, 1988 (53 FR 30566), in response to the 1987 signing of the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol).[1] The U.S. was one of the original signatories to the 1987 Montreal Protocol and the U.S. ratified the Protocol on April 21, 1988. Congress then enacted, and President Bush signed into law, the Clean Air Act Amendments of 1990 (CAA or the Act) that included Title VI on Stratospheric Ozone Protection.

Today's action amends the existing EPA regulations published under Title VI of the CAA that govern the production and consumption of ozone-depleting substances. Today's action establishes an exemption from the methyl bromide production and import reduction and phaseout schedule for quantities to be used for quarantine and preshipment applications. Today's amendments are intended to implement requirements of the Protocol and the CAA, including amendments to Title VI as created by Section 764 of the 1999 Omnibus Consolidated and Emergency Supplemental Appropriations Act (Pub. L. 105–277, October 21, 1998) (Section 604(d)(5) of the Clean Air Act).

The requirements contained in the final rules published in the **Federal Register** on December 20, 1994 and May 10, 1995 establish an Allowance Program. The Allowance Program and its history are described in the notice of proposed rulemaking (NPRM) published in the **Federal Register** on November 10, 1994 (59 FR 56276). The control and the phaseout of production and consumption of ozone-depleting substances, as required under the Protocol and CAA, are accomplished through the Allowance Program.

In developing the Allowance Program, EPA collected information on the amounts of ozone-depleting substances produced, imported, exported, transformed and destroyed within the United States for specific baseline years

[1] Several revisions to the original 1988 rule were issued on the following dates: February 9, 1989 (54 FR 6376), April 3, 1989 (54 FR 13502), July 5, 1989 (54 FR 28062), July 12, 1989 (54 FR 29337), February 13, 1990 (55 FR 5005), June 15, 1990 (55 FR 24490) and June 22, 1990 (55 FR 25812) July 30, 1992 (57 FR 33754), December 10, 1993 (58 FR 65018).

for specific chemicals. This information was used to establish the U.S. production and consumption ceilings for these chemicals. The data were also used to assign company-specific production and import rights to companies that were in most cases producing or importing during the specific year of data collection. For methyl bromide, 1991 was the baseline year used to establish the ceiling and assign company-specific production and import rights. Production or import rights are called ''allowances.'' Production allowances and consumption allowances continue to exist for only one specific class I controlled ozone-depleting substance—methyl bromide. All other production or consumption of class I controlled substances is prohibited under the Protocol and the CAA, save for a few narrow exemptions. For methyl bromide the remaining schedule for the phaseout of production and consumption allowances is as follows: 50 percent reduction of baseline beginning January 29, 2001, 70 percent reduction of baseline beginning January 1, 2003, and a 100 percent reduction of baseline beginning January 1, 2005, with narrow exemptions for critical uses and emergencies, as well as for quarantine and preshipment uses.

In the context of the regulatory program, the use of the term consumption may be misleading. Consumption does not mean the ''use'' of a controlled substance, but rather is defined as the formula: Consumption = production + imports − exports, of controlled substances (Article 1 of the Protocol and Section 601 of the CAA). Class I controlled substances that were produced or imported through the expenditure of allowances prior to their phaseout date can continue to be used by industry and the public after that specific chemical's phaseout under these regulations, unless otherwise precluded under separate regulations.

The specific names and chemical formulas for the controlled ozone-depleting substances in Groups of class I controlled substances are in Appendix A and Appendix F in Subpart A of 40 CFR Part 82. The specific names and chemical formulas for the class II controlled ozone-depleting substances are in Appendix B and Appendix F in Subpart A.

II. What Is Methyl Bromide?

Methyl bromide is used in the United States and throughout the world as a fumigant to control a variety of pests in many different situations. Methyl bromide is an odorless, colorless, toxic gas. Methyl bromide is a broad spectrum pesticide, which is used as a fumigant to control a variety of pests, such as insects, weeds, rodents, pathogens, and nematodes. Additional characteristics and details about the uses of methyl bromide can be found in the proposed rule published in the **Federal Register** on March 18, 1993 (58 FR 15014) and the final rule published in the **Federal Register** on December 10, 1993 (58 FR 65018). Information on methyl bromide can be found at the following sites of the World Wide Web: *www.epa.gov/ozone/mbr/mbrqu.html* and *www.teap.org* or by contacting the Stratospheric Ozone Protection Hotline at 1–800–296–1996.

III. What Are Examples of Quarantine and Preshipment Uses of Methyl Bromide?

An example of a quarantine use of methyl bromide is the fumigation of commodities such as rice and spices that are subject to infestation by a specific and officially recognized quarantine pest, such as the khapra beetle (Trogoderma granarium Everts). The purpose of quarantine fumigation is to prevent the introduction of specific quarantine pest(s) into a defined geographical area, such as an importing country. An example of a preshipment use of methyl bromide is the application to wheat because of official phytosanitary requirements at the shipment destination. In 1998, the Methyl Bromide Technical Options Committee (MBTOC), a sub-group under the independent advisory body of the Technical and Economic Assessment Panel (TEAP) to the Montreal Protocol, published an assessment that gives further details about uses of methyl bromide and possible alternatives and substitutes for controlling pests.

IV. What Is the Legal Authority for Exempting Production and Consumption of Methyl Bromide for Quarantine and Preshipment Applications?

In Article 2H of the Montreal Protocol, which establishes the phaseout schedule for methyl bromide for developed countries, paragraph 6 states that, ''[t]he calculated levels of consumption and production under this Article shall not include the amounts used by the Party for quarantine and pre-shipment applications.'' EPA notes that paragraph 6, of Article 2H indicates that the exemption is to exclude from the U.S.'s calculation of methyl bromide consumption and production the amounts used by the U.S. for quarantine and preshipment applications. In addition, Article 7 of the Protocol was recently amended regarding methyl bromide and now requires each Party to report on, ''the annual amount used for quarantine and preshipment applications.'' Beyond the critical uses allowed in Article 2H, Paragraph 5, quarantine and preshipment uses are the only exemptions explicitly allowed for under the Montreal Protocol.

The recent amendments to Title VI of the Clean Air Act regarding methyl bromide include a new provision on ''Sanitation and Food Protection,'' which is related to the Protocol exemption for quarantine and preshipment. This new Section 604(d)(5) of Title VI of the CAA, on Sanitation and Food Protection, was added by Section 764(b) of the 1999 Omnibus Consolidated and Emergency Supplemental Appropriations Act (Public Law 105–277). This new Section 604(d)(5) says, ''To the extent consistent with the Montreal Protocol's quarantine and preshipment provisions, the Administrator shall exempt the production, importation, and consumption of methyl bromide to fumigate commodities entering or leaving the United States or any State (or political subdivision thereof) for purposes of compliance with Animal and Plant Health Inspection Service requirements or with any international, Federal, State or local sanitation or food protection standard.'' Prior to Congressional passage of Section 604(d)(5), the CAA did not provide authority for creating such an exemption to the methyl bromide phaseout schedule. Therefore, by today's interim final regulation, EPA is implementing the express language provided in Article 2H, paragraph 6, of the Protocol under the authority provided by section 604(d)(5) of the CAA. EPA is also acting in a manner consistent with, and to fulfill the obligations of, section 614(b) of the CAA. Section 614(b) of the CAA states that, ''[t]his title as added by the Clean Air Act Amendments of 1990 shall be construed, interpreted, and applied as a supplement to the terms and conditions of the Montreal Protocol, as provided in Article 2, paragraph 11 thereof, and shall not be construed, interpreted, or applied to abrogate the responsibilities or obligations of the United States to implement fully the provisions of the Montreal Protocol. In the case of conflict between any provision of this title and any provision of the Montreal Protocol, the more stringent provision shall govern.''

At a July 1999 meeting with the Methyl Bromide Industry Panel, EPA received a legal memorandum from their counsel regarding the definition of quarantine and preshipment and the recent amendment adding Section

604(d)(5) to the Clean Air Act. The argument made in the Methyl Bromide Industry Panel's legal memorandum is that the introductory phrase (''to the extent consistent with the Montreal Protocol's quarantine and pre-shipment provisions'') in Section 604(d)(5) of the Clean Air Act does not require EPA to make its regulations consistent with the ''preshipment'' and ''quarantine'' definitions in Decision VII/5 and Decision XI/12 of the Parties to the Protocol. The issue raised by the Methyl Bromide Industry Panel's legal memorandum is whether the reference to the ''Montreal Protocol's quarantine and preshipment provisions,'' in Section 604(d)(5) refers only to the single provision found in Article 2H, paragraph 6 of the Protocol (which provides that the ''calculated levels of consumption and production under this Article shall not include the amounts used by the Party for quarantine and preshipment applications'') or also refers to Decision VI/11, Decision VII/5, Decision XI/12, and Decision XI/13 of the Parties. The Methyl Bromide Industry Panel's legal memorandum also notes that Section 602 of the CAA defines the Montreal Protocol as, The Montreal Protocol on Substances that Deplete the Ozone Layer and its amendments and adjustments without specific reference to Decisions by the Parties to the Protocol.

The provisions of the Vienna Convention on the Law of Treaties (VCLT), 8 International Legal Materials 679 (1969), that concern treaty interpretation generally reflect customary international law. Article 31 of the VCLT sets forth the general rule of treaty interpretation. Paragraph 1 of Article 31 provides that a treaty ''shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.'' Paragraph 3 of Article 31 of the VCLT states, ''[t]here shall be taken into account, together with any context: * * * (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions.'' Decisions VI/11, VII/5, XI/12 and XI/13 constitute subsequent consensus agreements among the Parties to the Montreal Protocol (including the United States) regarding the interpretation and application of the quarantine and preshipment provision of Article 2H. Therefore, it is appropriate for EPA, when determining what is consistent with the ''Montreal Protocol's quarantine and preshipment provisions,'' to take into account Decisions VI/11, VII/5, XI/12, and XI/13.

Furthermore, in amending the CAA, Congress specifically cited the plural ''quarantine and preshipment provisions.'' If Congress intended for this phrase to be limited to the single provision in the Protocol referencing quarantine and preshipment in Article 2H, and not the subsequent Decisions between the Parties regarding interpretation or application of the treaty, Congress would have presumably directed the Agency to be consistent with the singular provision.

Precedents within the current regulations (40 CFR Part 82) demonstrate that the United States has routinely considered Decisions that clarify and interpret obligations under the Montreal Protocol to be authoritative and that such Decisions of the Parties are currently implemented through regulations under the CAA. For example, the United States' current regulatory definition of a ''controlled substance'' is based on a Decision by the Parties (Decision IV/12) that clarifies Article 1, paragraph 4 of the Protocol.

In another example, the current process in the United States for implementing the Protocol's essential-use exemption relies on Decisions by the Parties for the specific definition of what is an ''essential use.'' In the process of preparing the United States' annual nomination, the U.S. relies on Decision IV/25 to evaluate applications that are submitted by U.S. entities who are requesting an essential-use exemption. In addition, the U.S. government considers whether the information that will be provided in the national nomination is in accordance with Decision VIII/10, as well as whether it is in accordance with the conditions to be applied in providing an exemption under Decision VI/9, Decision VII/28, and Decision VIII/9. Consideration of these Decisions by the U.S. government is important because the U.S. nomination is reviewed by the Protocol's TEAP, who then makes recommendations to the Parties based on the Decisions. The essential-use exemptions nominated by the U.S. government are ultimately considered and authorized by the Parties in the context of these Decisions. The control measures in Article 2 of the Protocol allow for essential-use exemptions (for the production and consumption of controlled substances beyond phaseout dates). However, the Parties' interpretation of the phrase ''essential use'' and their agreements regarding the application of this exemption appear in Decisions.

Finally, EPA is in the process of developing regulations that would implement Decision IX/7 of the Parties by allowing an exemption for ''emergency methyl bromide use.'' Decision IX/7 reflects an agreement among the Parties to the Protocol regarding the interpretation and application of the critical-use exemption provided for in Article 2H(5) of the Protocol. Decision IX/7 directs the Ozone Secretariat and the TEAP to ''evaluate the [emergency] use according to the ''critical methyl bromide use'' criteria and present this information to the next meeting of the Parties for review * * *''

The examples above illustrate how U.S. regulations incorporate Decisions by the Parties to the Protocol. Other precedents for incorporating Decisions by the Protocol Parties into current U.S. regulations can be found in 40 CFR Part 82, Subpart A.

V. What Is the Definition of Quarantine and Preshipment Applications?

In today's action, EPA is defining quarantine and preshipment applications as agreed by the Parties to the Montreal Protocol. The Parties to the Protocol agreed to the following definition of ''quarantine applications'' in Decision VII/5: ''quarantine applications, with respect to methyl bromide, are treatments to prevent the introduction, establishment and/or spread of quarantine pests (including diseases), or to ensure their official control, where: (i) Official control is that performed by, or authorized by, a national plant, animal or environmental protection or health authority; (ii) quarantine pests are pests of potential importance to the areas endangered thereby and not yet present there, or present but not widely distributed and being officially controlled.''

The Parties to the Protocol first agreed to the following definition for preshipment applications of methyl bromide in Decisions VI/11 and VII/5: ''preshipment applications are those treatments applied directly preceding and in relation to export, to meet the phytosanitary or sanitary requirements of the importing country or existing phytosanitary or sanitary requirements of the exporting country.'' At the 11th Meeting of the Parties in December 1999, the Parties further clarified the intent of the term preshipment, by agreeing to the following definition in Decision XI/12: ''* * * preshipment applications are those non-quarantine applications within 21 days prior to export to meet the official requirements of the importing country or existing official requirements of the exporting

country. Official requirements are those which are performed by, or authorized by, a national plant, animal, environmental, health or stored product authority.''

With today's action, EPA is defining quarantine applications and preshipment applications, for implementing the exemption to the methyl bromide production and consumption phaseout schedule mandated by the new section 604(d)(5) of the CAA and in a manner consistent with section 614(b) of the CAA, as follows:

Quarantine applications, with respect to class I, Group VI controlled substances, are treatments to prevent the introduction, establishment and/or spread of quarantine pests (including diseases), or to ensure their official control, where: (i) Official control is that performed by, or authorized by, a national plant, animal or environmental protection or health authority; (ii) quarantine pests are pests of potential importance to the areas endangered thereby and not yet present there, or present but not widely distributed and being officially controlled.

Preshipment applications, with respect to class I, Group VI controlled substances, are those non-quarantine applications within 21 days prior to export to meet the official requirements of the importing country or existing official requirements of the exporting country. Official requirements are those which are performed by, or authorized by, a national plant, animal, environmental, health or stored product authority.

As specified in the above definitions, which mirror exactly those specified by the Protocol, a quarantine application of methyl bromide must be ''performed by, or authorized by, a national plant, animal or environmental protection, or health authority.'' In addition, as delineated in the above definition, quarantine applications must be directed at quarantine pests. Today's definition of preshipment applications is limited to applications ''to meet the official requirements of the importing country or existing official requirements of the exporting country.'' The definition of preshipment applications specifies that the phrase ''official requirements'' means ''those which are performed by, or authorized by, a national plant, animal, environmental, health, or stored product authority.''

A. Are There Clarifications Regarding Trade Within the U.S.?

The Technical and Economic Assessment Panel (TEAP) provided the Parties to the Protocol with analyses and clarifications of the definition of ''quarantine applications,'' recommending that Decision VII/5 be interpreted to include officially required treatments for intra-country trade within the territory of the Party. Therefore, for purposes of today's regulation, ''quarantine applications'' include inter-state and inter-county treatments required to control quarantine pests. This is consistent with the Montreal Protocol and reconciles the language with Section 604(d)(5) of the CAA on Sanitation and Food Protection, which refers to international, Federal, state and local requirements. In recognizing official state, county, tribal, and local quarantine requirements, EPA interprets the definition of quarantine applications such that intra-country quarantine treatments required by state, county, tribal, and local plant, animal, environmental, or health government authorities constitute official control.

In contrast to the definition of quarantine applications, which accommodates intra-country trade, the Protocol definition of preshipment applications is specific to trade between countries because of the phrase ''applications within 21 days prior to export.'' Therefore, for purposes of today's regulation, the exemption for preshipment applications is limited to the movement of goods from the U.S. to another country, and does not include movement of goods within the U.S.

B. Are There Additional Qualifiers Associated With the Definition of Preshipment Applications?

In 1998, the TEAP provided interim explanatory notes to assist the Parties in the consistent implementation of the exemption for preshipment applications, highlighting that preshipment applications are ''* * * not intended to cover informal or purely contractual or commercial arrangements not required under official regulations.'' (April 1998 TEAP Report, page 145). The definition of ''preshipment applications'' focuses on applications ''to meet the official requirements of the importing country or existing official requirements of the exporting country.'' The definition of preshipment applications specifies that the phrase ''official requirements'' means ''those which are performed by, or authorized by, a national plant, animal, environmental, health, or stored product authority.''

The definition of preshipment applications in Decision XI/12 contains the phrase ''existing official requirements of the exporting country,'' (emphasis added), which implies the need to establish a cutoff date when a preshipment requirement is existing. With today's action, however, for the interim period through December 31, 2002, EPA will interpret the word ''existing'' to mean simply that the preshipment requirement must be in existence at the time of the specific treatment. It is important to note that the exporting country referred to in the phrase is the United States.

EPA is seeking comments on ways to interpret the term ''existing'' in the preshipment applications definition for development of the final version of this regulation. Options for interpreting the term ''existing official requirements'' might be to exempt official preshipment requirements of the exporting country that were: (1) In effect prior to the date the Parties to the Protocol adopted Decision XI/12, which was December 3, 1999, (2) in effect at the time this interim final rule is published in the **Federal Register**, (3) in place at the time the final rule on the quarantine and preshipment exemption is published in the **Federal Register**, (4) existing at the time of the methyl bromide application (since it would be an ''existing'' requirement of the exporting country upon going into effect). EPA seeks comments on these possible interpretations of the phrase ''existing official requirements of the exporting country.''

For the interim period through December 31, 2002, EPA will also interpret the phrase ''to meet the * * * official requirements of the exporting country'' as exempting methyl bromide used to fumigate a commodity when it is to meet a United States food sanitation requirement and the fumigation occurs within 21 days prior to export from the United States. For example, today's action considers methyl bromide used to meet food sanitation requirements of the U.S. government (such as requirements for food in interstate commerce under the Federal Food Drug and Cosmetic Act, as monitored by the Food and Drug Administration) to be exempt under the definition of preshipment applications for the interim period through December 31, 2002, when the methyl bromide is applied within the 21 days prior to export to a foreign country. EPA is seeking comments on this interpretation of the definition of ''preshipment applications.''

It should be noted that if an importing country were to establish a new official requirement for the preshipment application of methyl bromide, nothing in this rule would prevent a U.S. exporter from using methyl bromide to meet the new requirement of the importing country.

C. Are There Additional Qualifiers Associated With the Definition of Quarantine Applications?

With today's action, EPA is establishing that for the interim period through December 31, 2002, the exemption for quarantine applications will apply when methyl bromide is among a list of treatments or official control options for quarantine pests or if methyl bromide is required for an emergency U.S. quarantine application. Under Section 3, Section 18, and Section 24a of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA is notified of emergency quarantine applications of methyl bromide in accordance with specific requirements published under FIFRA. In addition, for the interim period (through December 31, 2002), methyl bromide will be exempted for quarantine applications on U.S. commodities for export when the foreign country simply has a broad performance-based quarantine requirement. In other words, today's action exempts methyl bromide in situations when the foreign country's regulations require a certification that U.S. commodities be exported free of quarantine pests. EPA understands that both USDA/APHIS and State agencies issue ''phytosanitary certificates'' that accompany U.S. commodities exported to foreign countries. These phytosanitary certificates are often required by importing foreign countries to ensure that U.S. exports are free of quarantine pests. To the extent that methyl bromide is used by a U.S. exporter to meet a foreign quarantine requirement, then the phytosanitary certificates (PPQ Form 577, PPQ Form 578, and PPQ Form 579) issued by USDA/APHIS or an authorized State agency will be an additional means for EPA to cross-check quarantine applications of methyl bromide under today's exemption. However, EPA is not exempting methyl bromide used for non-quarantine applications, even if the U.S. exporter must obtain a phytosanitary certificate for the export of the commodity. Today's exemption applies to the use of methyl bromide to meet a foreign quarantine requirement when a phytosanitary certificate is issued for a U.S. exported commodity. If PPQ Forms or other types of certificates are issued for commodities meeting state or local quarantine requirements then methyl bromide used in these cases is considered exempt under today's action.

To assist in development of the final version of this regulation, EPA is seeking comments on the variety of ways of interpreting the methyl bromide exemption for quarantine applications. One approach would be to limit the exemption to cases when regulations list methyl bromide as the unique treatment or control for specific quarantine pests.

A second approach would be to apply the exemption in cases when methyl bromide is among a list of treatment or control options for quarantine pests. Presumably, currently existing quarantine regulations that include methyl bromide among a list of treatment or control options indicate that other treatments or controls on the list can be used to address the quarantine pest(s).

A third approach would be to apply the exemption in cases when methyl bromide is required for an emergency quarantine application.

A fourth approach would be to apply the exemption to quarantine applications when there is a broad performance-based quarantine requirement. This would be a situation when the regulations require that a commodity be exported/imported free of quarantine pests. The Agency understands that many importing countries have quarantine regulations which broadly require commodities to be free of quarantine pests without specifying the types of treatments or controls. EPA seeks comment on these various ways of interpreting the exemption for quarantine applications.

Combinations of the above approaches for applying the exemption for quarantine applications, including combinations where the exemption is applied differently depending on whether a commodity is being imported into, moved within, or exported from the U.S., are possible as demonstrated by the conditions established with today's action for the interim period through December 31, 2002 (first paragraph in V.C. above). Today's action exempts methyl bromide for imports when methyl bromide is among a list of treatments or official control options for quarantine pests or if methyl bromide is required for an emergency U.S. quarantine application, and exempts methyl bromide for exported U.S. commodities when the foreign country simply has a broad performance-based quarantine requirement. Another possible combination of the above approaches would be to institute the exemption for treatments of commodities being imported into the U.S., or moved within U.S., when the quarantine regulations uniquely list methyl bromide as the treatment/control option, while at the same time exempting methyl bromide for the export of U.S. commodities when the foreign quarantine requirement lists methyl bromide among a list of treatment/control options. In this latter example for exports, the exemption might apply only in cases when a phytosanitary certificate is issued for a U.S. commodity to meet the foreign quarantine requirement and methyl bromide is among the list of treatment/control options. EPA is seeking comments on the approaches above and possible combinations of these as demonstrated by the conditions established with today's action for the interim period through December 31, 2002.

The Agency intends to consider prior Decisions by the Parties to the Protocol, such as paragraph (c) of Decision VII/5 which states, ''[i]n applying these definitions, all countries are urged to refrain from use of methyl bromide and to use non-ozone-depleting technologies wherever possible.'' Further, the Parties to the Protocol agreed in Decision XI/13, ''to request the Parties to review their national plant, animal, environmental, health and stored product regulations with a view to removing the requirement for use of methyl bromide for quarantine and preshipment where technically and economically feasible alternatives exist.'' The need to have incentives for people to switch to non-ozone-depleting methods for controlling quarantine pests will also be included in development of the final version of this regulation and EPA is seeking comments on this issue.

EPA is interested in comments addressing the effect of each of these potential approaches on methyl bromide use. EPA recognizes that the price of methyl bromide will play a key role in determining uses, especially where alternatives are available. Basic economic principles of supply and demand suggest that the price of methyl bromide is likely to increase during the phaseout period as supply is constrained. A question remains as to whether this increase will also be seen in the price of quantities of methyl bromide exempted for quarantine and preshipment applications, or whether the exempted methyl bromide for quarantine and preshipment applications will be priced differently than non-exempt quantities. We are interested in comments that address the merits of relying on a potential price increase for methyl bromide exempted for quarantine and preshipment applications—at least over the initial phaseout period—as a way of governing its use for these purposes.

D. How Do the Definitions of Quarantine and Preshipment Aplications Apply to Food Sanitation?

With today's action, for the interim period through December 31, 2002, the exemption of methyl bromide for quarantine applications will not apply to preventative treatments to meet food sanitation standards. Please note that if the methyl bromide use were to occur within 21 days prior to export to another country it would be exempted under the definition of ''preshipment applications'' if it was to meet the official requirements of the importing country or existing official requirements of the exporting country (see discussion in Part V.B. above).

Some U.S. industries have stated that not having methyl bromide for the preventative treatment of their commodities against non-quarantine pests could jeopardize their ability to bring the commodity to market because they would not be able to meet food sanitation standards. EPA is aware that alternative treatments may be technically and economically available for many industries currently using methyl bromide to maintain food sanitation or meet food sanitation standards.

For those industries facing food sanitation challenges, production of methyl bromide will continue until the 2005 phaseout, albeit in limited quantities. For the period beyond the 2005 phaseout, these industries, as well as others, will be able to apply for a ''critical-use'' exemption for continued production and/or import of methyl bromide. Consistent with the Protocol, Parties can apply for a critical-use exemption beyond the 2005 phaseout for specific uses where there are no technically and economically feasible alternatives. Although the critical-use exemption is not available until after 2005, EPA has initiated a separate process with stakeholder input to develop a critical-use exemption. In 2002, a separate **Federal Register** notice will be published asking for people to submit specific information to substantiate requests for a critical-use exemption. However, at this time no decisions have yet been made regarding what uses will be exempted as ''critical.''

EPA understands that certain industries often use methyl bromide as a prophylactic treatment for periodic quality control fumigations associated with food sanitation. Stored commodities, such as dried fruits, nuts, and cocoa beans, as well as grain mills and pasta manufacturing facilities are often fumigated periodically with methyl bromide to prevent populations of pests, such as insects and rodents, from increasing to a point where they would adversely affect food quality. Fumigations with methyl bromide of stored commodities, or food-processing facilities, as preventative measures to maintain food sanitation are directed at controlling populations of pests that are generally endemic to the U.S. and are not designed or intended to ''prevent the introduction, establishment and/or spread of quarantine pests.'' Congress directed EPA to create an exemption, ''consistent with the Montreal Protocol's quarantine and preshipment provisions.'' The quarantine definition from Decision VII/5 of the Protocol stresses that exempt applications of methyl bromide are ''to prevent the introduction, establishment and/or spread of quarantine pests (including diseases).'' This focus on ''quarantine pests'' seems to be the core of the definition and establishes the limit on exempted quarantine applications.

The definition of preshipment applications from Decision XI/12 includes a time constraint of ''21 days prior to export,'' which establishes the limit on the exempted preshipment uses. Thus, the periodic prophylactic fumigation of a commodity, or, the prophylactic fumigation of a food-processing facility which is not to meet quarantine requirements and which is outside of the 21 days prior to export would not be exempt under the Protocol's definition of quarantine applications or preshipment applications.

The Agency is seeking comments on the prophylactic uses of methyl bromide to meet food sanitation standards. The Agency intends to use this information to assist in development of the critical-use exemption process as discussed above.

E. How Do These Definitions Apply to ''Propagative Material''?

The use of methyl bromide to fumigate the soil for growing propagative material, such as strawberry propagative rhizomes, differs from many quarantine applications of methyl bromide. In the specific example of quarantine treatment of strawberry propagative material that was brought to EPA's attention, Japanese regulations require that the underground portions of the imported propagative rhizomes (of the strawberry planting stock) be certified to have been grown in soil that is free of quarantine pests. To meet this Japanese quarantine requirement, and other similar quarantine requirements, U.S. nurseries fumigate the soil with methyl bromide to raise strawberry propagative material. Methyl bromide is used to fumigate the soil before each transplanting (a number of times over 3–5 years) because Japanese requirements dictate that soil in which the strawberry propagative rhizomes are grown be free of quarantine pests. EPA is unaware of how much methyl bromide is used in the growing of strawberry propagative material in the U.S. to meet this or other foreign or domestic quarantine requirements and seeks comments on this specific quarantine application. In addition, the Agency is seeking similar information on other types of plants for planting for which methyl bromide is used as a pre-plant treatment (soil treatment) to ensure propagative materials meet quarantine requirements.

With today's action, for the interim period through December 31, 2002, the exemption for quarantine applications applies to methyl bromide used for growing propagative material, such as strawberry rhizomes, if the methyl bromide is being used to grow propagative material to meet official quarantine requirements of the destination to which it will be shipped. To ensure that the use of methyl bromide for propagative material is consistent with the Protocol's quarantine provisions, applicators availing themselves of the exemption during the interim period must maintain records of each methyl bromide application. These records must certify that the methyl bromide treatments are being undertaken to meet quarantine requirements of the intended destination country for the specific propagative material.

Monitoring methyl bromide used for propagative materials will be a large challenge. The propagative materials may be grown in close proximity to crops that do not qualify for the quarantine and preshipment exemption. EPA believes that it may be difficult to ensure that farmers growing propagative material in a small nursery in the corner of their acreage were meeting the requirements associated with the quarantine exemption—that the methyl bromide purchased under the exemption for the nursery was only used for the propagative material—and growers were not using the methyl bromide for fumigation of their larger acreage where the actual crop was being grown (*i.e.,* strawberry fruit versus propagative material). Monitoring for such an abuse of the exempted methyl bromide may be difficult because both uses would be soil fumigations on the same farm—in adjoining fields.

Another difficulty in compliance monitoring may be caused by the 3–5 year time horizon for growing

strawberry propagative materials. The growing cycle for strawberry propagative materials necessitates soil fumigation with methyl bromide several times over a 3–5 year period to protect the specific germplasm (genetic material) that is desired by the Japanese, or others, as well as to allow the grower to certify that the underground portions of the propagative plants are free of quarantine pests. A system is needed to document and ensure the validity of claims by farmers that they are using exempted methyl bromide over the 3–5 years to grow strawberry seedlings for export to meet Japanese or other quarantine requirements. However, EPA recognizes that some farmers will legitimately justify using exempted methyl bromide to meet Japanese or other quarantine requirements for strawberry seedlings, yet due to economic or market conditions these farmers will not send the seedlings to Japan or another destination that has a relevant quarantine requirement. To address this compliance monitoring challenge, the Agency is seeking comments on establishing a recordkeeping requirement for quarantine applications that involve the use of methyl bromide in soil fumigation for the growth of propagative material. EPA is also seeking comments on whether the U.S. growers of propagative materials, in general, should be required to report periodically on methyl bromide used to meet quarantine requirements.

The use of exempted methyl bromide to grow propagative material that the grower planned to ship to a destination with a propagative material quarantine requirement, but which the grower ultimately shipped to a destination without such a requirement, may raise compliance issues for the United States' obligations under the Protocol. EPA is seeking comments on the necessity of, and the nature of, possible compensatory measures. If methyl bromide is used to grow propagative material with the intention of meeting a quarantine requirement of a particular importing country or domestic location, but in the end is sent instead to a destination without a quarantine requirement for the propagative material, the use of the methyl bromide is not exempt under the Protocol. Rather, the quantity used would count against the United States' cap for domestic methyl bromide consumption (currently limited to 50% of baseline for 2001). The U.S. could exceed its control obligations under the Protocol if all U.S. production and consumption allowances for methyl bromide were expended in a particular control period (calendar year) and some methyl bromide in the same control period was mistakenly exempted for quarantine applications when, in fact, the propagative material was sent to a place without quarantine requirements. EPA is seeking comments on several possible options for rectifying this potential situation of non-compliance.

Under the first approach, a person who uses exempted methyl bromide to meet a propagative material quarantine requirement, and who ultimately changes the material's destination to one without a quarantine requirement, would be required to buy an equivalent amount of production allowances for any ozone-depleting substance, on an ozone-depleting potential (ODP) basis, and retire those allowances. In other words, the allowances could not be expended for new production in accordance with Subpart A of 40 CFR Part 82. For example, if a person used 1,000 kilograms of exempted methyl bromide on strawberry propagative material to meet the quarantine requirement of the intended destination but delivered the propagative material to a destination without a quarantine requirement, that person would be required to purchase the ODP equivalent of 1,000 kilograms of methyl bromide production allowances to compensate for the United States' exceeding the methyl bromide production cap.

A second approach would be for the person to destroy an amount of ozone-depleting substances that is equivalent on an ODP basis. Thus, the person would be required to purchase and destroy quantities of existing stocks of ozone-depleting substances, rather than being required to purchase and retire allowances, as in the first approach.

A third approach would require the person to purchase, and store, a quantity of non-exempt methyl bromide equivalent to the quantity of exempt methyl bromide used in the growing of propagative material. This stored (banked) quantity of non-exempt methyl bromide would be insurance against the need to compensate for the United States' specific methyl bromide compliance obligations of zero production after the phaseout, or in the case when all production and consumption allowances had been expended for the particular control period prior to the phaseout. If, in this third option, the propagative material was in fact sent to a destination with a quarantine requirement for that particular propagative material, the person could then sell or use the quantity of non-exempt methyl bromide that was being stored as ''insurance''. However, if the propagative material was ultimately sent to a destination without a quarantine requirement and compensatory measures were needed to ensure the United States meets its compliance obligations under the Protocol, the person holding the stored quantity of non-exempt methyl bromide would be required to pay for its destruction. This option addresses issues of the long time horizon between methyl bromide use and the shipment of the propagative material, as well as the United States' specific methyl bromide compliance obligations under the Protocol both before and after the phaseout.

EPA is seeking comments regarding compliance and enforcement issues related to soil uses of methyl bromide for propagative material to meet quarantine requirements, in general, as well as the specific approaches described above. In addition, the Agency is seeking information on existing certification programs and recordkeeping requirements associated with the pre-plant soil use of methyl bromide for growing propagative material to meet quarantine requirements. EPA is seeking comments on the possible recordkeeping and reporting aspects of the specific approaches described above for rectifying possible non-compliance. Resolving these compliance monitoring and enforcement issues will be important not only to ensure U.S. compliance with obligations under the Protocol but also to maintain a level playing field for all growers in each particular commodity market.

F. How Do These Definitions Apply to In-Transit Applications?

With today's action, for the interim period through December 31, 2002, quantities of methyl bromide used to control quarantine pests on commodities in-transit to the U.S. or traveling within the U.S. are exempt when the use is to meet a quarantine, official control requirement that lists methyl bromide (see discussion in Part V.C. above). Quantities of methyl bromide used to control quarantine pests on commodities that are in-transit from the U.S. to another country, to meet the importing country's quarantine requirements, are also exempt. However, for the interim period, the in-transit application of methyl bromide after a shipment leaves the United States is not an exempt preshipment application because the application would not occur ''within 21 days prior to export'' from the United States (emphasis added). As above, it should

be noted that for purposes of today's regulation, the word ''export'' is interpreted to mean the departure of a commodity from the United States or another foreign country.

EPA is seeking comments on the extent of the practice of fumigating commodities for non-quarantine purposes while in-transit.

VI. What Is the Process for Exempting Methyl Bromide for Use in Quarantine and Preshipment Applications?

With this action, EPA is establishing a process to exempt methyl bromide used for quarantine and preshipment applications from the Allowance Program's control measures that phase out production and consumption of methyl bromide (described in Part I. Background above). Today's action exempts quantities of methyl bromide used for quarantine and preshipment applications from the production and consumption reduction steps through December 31, 2002. The final version of this rule will address the exemption for quantities of methyl bromide used for quarantine and preshipment applications for the period that includes the remaining reduction steps and the eventual phaseout of production and consumption under the Montreal Protocol and Clean Air Act.

EPA is creating a flexible process for exempting production and consumption of methyl bromide for quarantine and preshipment applications that is responsive to demands arising when commodities need to be protected from infestations by quarantine pests and when commodities need to be protected immediately prior to shipment in accordance with official requirements. Today's action includes a certification and reporting procedure under authority of the Clean Air Act (CAA) that exempts production and consumption of methyl bromide for quarantine and preshipment applications from the reduction steps through December 31, 2002.

A. Are Producer and Importer Quarterly Reports and Recordkeeping Changing?

Producers and importers must distinguish between quantities of methyl bromide produced or imported for quarantine and preshipment applications and quantities produced or imported for other categories, such as transformation, when submitting quarterly reports that are otherwise currently required under § 82.13. As with quantities for transformation, the quantities of methyl bromide produced or imported for quarantine and preshipment applications are exempt, and are not counted against a company's production allowances and consumption allowances. In other words, the quantity reported specifically for quarantine and preshipment applications by the producer or importer will not be counted when determining the production allowances and consumption allowances expended during the quarter. The production allowances and consumption allowances held by each U.S. company at the beginning of the year, in accordance with § 82.5, § 82.6 and § 82.7, establish the U.S. limit on the amount of production and consumption of methyl bromide for all non-exempted uses in accordance with obligations under the Montreal Protocol. The relationship between each company's baseline production allowances and baseline consumption allowances and the reduction steps in these allowances is in accordance with the control measures under the Montreal Protocol and the Clean Air Act as described in Part I of today's rule and in the direct final rule published in the **Federal Register** on November 28, 2000 (65 FR 70795).

Methyl bromide produced or imported and specifically designated for quarantine and preshipment applications will not be counted as net production or net import for the purposes of the Allowance Program. Net production or net import represents the number of production allowances and consumption allowances expended by a company. Currently, producers and importers provide information on the gross quantity of methyl bromide produced or imported in a quarter. In the same quarterly report, producers and importers indicate the quantity specifically designated for transformation and the quantity specifically designated for destruction which are exempt from the reduction steps and phaseout. These quantities for transformation and for destruction are subtracted from the gross quantity in order to calculate a company's net production or net import. With today's action, producers and importers must also provide information on the quantity of methyl bromide designated solely for quarantine and preshipment applications. This quantity of methyl bromide solely for quarantine and preshipment applications is exempt and producers and importers should also subtract it from the gross quantity in order to calculate net production or net import. Finally, domestic purchasers (distributors or customers) must provide producers and importers with certifications of the quantities being purchased that are designated solely for quarantine and preshipment applications (discussion of requirements for foreign purchasers appears below in Part VI.D). Certifications from distributors will attest that the material will be sold only for quarantine and preshipment applications, and certifications from applicators purchasing directly from a producer or importer will attest that the material will be used only for quarantine and preshipment applications.

In developing today's regulation, EPA initially considered a system of refunding allowances to producers and importers based on amounts of methyl bromide certified as having been purchased solely for quarantine and preshipment applications reported to the Agency by distributors. However, EPA decided a process of refunding allowances would be time-consuming and would likely impede the commercial availability of methyl bromide. EPA also believes a process of refunding allowances to producers and importers based on certification of purchases solely for quarantine and preshipment applications would be more burdensome to implement for both the industry and the Agency. With this action, EPA is simply exempting through December 31, 2002, methyl bromide production and import for quarantine and preshipment applications from the requirement to expend allowances, as is currently done for methyl bromide for transformation or destruction.

In developing today's action, EPA also considered another option for exempting methyl bromide for quarantine and preshipment applications. EPA considered a procedure that would allow the Agency to follow specific quantities of quarantine or preshipment methyl bromide through the chain of commerce (similar to a RCRA hazardous waste manifest) but rejected this option as being overly burdensome with little additional benefit. The option of a manifest system to track quarantine and preshipment quantities through the market would have relied on methyl bromide's regulation under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). As a FIFRA regulated substance, cylinders of methyl bromide are marked with unique registration numbers and labels that prescribe the use of the substance. Although EPA is not tracking cylinders by registration number through the chain of commerce, the Agency is still working with industry on a possible change to the FIFRA label (see Part VI.E below) which would reflect requirements of this rulemaking under CAA authority. If the

FIFRA label on methyl bromide is changed in the future to create a unique product solely for quarantine and preshipment applications, in accordance with the provisions of the Protocol and CAA, then EPA believes identifying material that is exempt because it is designated explicitly for quarantine and preshipment applications will be facilitated.

B. Are Methyl Bromide Applicators Required To Report?

Today's action includes a certification requirement for purchases of methyl bromide by applicators. Applicators must submit a certification to the seller of the methyl bromide when they want to purchase a specific quantity of methyl bromide explicitly for quarantine and preshipment applications. The applicator will certify that the quantity purchased will be used solely for quarantine and preshipment applications. The applicator must send the certification to the company selling the methyl bromide before the seller ships the cylinders of methyl bromide (*i.e.,* certification before shipment).

With today's action, for the interim period through December 31, 2002, the distributor must send a Quarantine and Preshipment Certification Form to any person who places an order for a quantity of methyl bromide that is explicitly and solely for quarantine and preshipment applications as defined in today's action. The applicator, upon receiving the form, must check the box indicating that the particular quantity being ordered is solely for quarantine and preshipment applications as defined on the form (the definition above in Part V) and will neither be sold nor used for any other purpose. The applicator must sign the form certifying, under penalty of law, that the quantity of methyl bromide purchased will be used solely for quarantine and preshipment applications in accordance with the definitions. The applicator must return the completed and signed form to the distributor. The distributor retains the certification form in order to compile data that they will submit to EPA on the quantity of methyl bromide purchased under the exemption for quarantine and preshipment applications. The certification form ensures that quantities of methyl bromide produced or imported under the exemption for quarantine and preshipment applications are used only in accordance with the strict requirements of the exemption. It is important to note that the applicator will also be able to purchase non-exempt methyl bromide until the phaseout date for methyl bromide.

Today's interim rule does not require the distributor to send a Certification Form for every methyl bromide purchase '' instead, distributors are only required to send a Certification Form when an applicator wants to purchase a quantity solely for quarantine and preshipment applications. However, the distributor of methyl bromide may want to send the Certification Form to customers (applicators) for every methyl bromide quantity before the actual purchase and shipment of the material. Doing so would allow the distributor and the applicator to distinctly track the quantities of exempt and non-exempt methyl bromide. To assist in developing the final rule, EPA is seeking comments on the merits and burdens associated this type of shipment-by-shipment certification method as compared to the approach outlined in today's rule. EPA is also interested in comments addressing the implications of a FIFRA label for exempt quantitites of methyl bromide (as discussed in Part VI.E. below).

For quarantine applications, the applicator must collect documentation citing the regulatory requirement or other official requirement that justifies the use of methyl bromide. Acceptable documentation for a quarantine application includes the forms provided directly to the applicator by an official from a national plant, animal, environmental protection or health authority requesting the treatment of commodities to control quarantine pests. In the absence of official documentation from a plant, animal, environmental protection or health authority, the commodity owner, shipper or their agent must provide a letter to the methyl bromide applicator requesting the use of methyl bromide that explicitly cites the regulation requiring a quarantine treatment or quarantine official control. Likewise, the applicator must collect documentation citing the official requirement calling for a preshipment application. The commodity owner, shipper or their agent must provide a letter to the methyl bromide applicator requesting the use of methyl bromide that explicitly cites the official requirement for a preshipment application. The letter that the commodity owner, shipper or their agent presents to the applicator must include the following statement: ''I certify knowledge of the requirements associated with the exempted quarantine and preshipment applications published in 40 CFR part 82, including the requirement that this letter cite the treatments or official controls for quarantine applications or the official requirements for preshipment requirements.'' Both the commodity owner, shipper or their agent and the applicator must maintain this letter for three years in accordance with current recordkeeping requirements in 40 CFR part 82, subpart A. Neither the applicator nor the commodity owner, shipper or their agent are required to submit the letter to EPA. EPA is seeking comments on these procedures, for purposes of developing the final rule.

C. Are Distributors Required To Report?

With today's action, for the interim period through December 31, 2002, EPA is requiring that a person who distributes methyl bromide to applicators (the distributor) compile all the information from applicator certifications (as described in Part VI.B, above) on an annual basis and submit the summary data to EPA. If certifications were signed by applicators at the time the specific quantity of methyl bromide was ordered, in accordance with the procedures described above in VI.B. but the signature of the certification was before date of today's publication, then the distributor can consider those quantities exempt and should include them in the annual report to EPA. In other words, if certifications were signed contemporaneously with an order for a quantity of methyl bromide solely for quarantine and preshipment applications, the distributor should include this quantity in their annual report to EPA, as long as the certifications were signed within the 2001 or 2002 control periods (calendar years).

In development of the final version of this regulation, EPA is seeking comments on whether annual, bi-annual or quarterly reporting of this information would be easier to manage for the distributors of methyl bromide. Companies responsible for reporting on other ozone-depleting substances have clearly expressed their preference for quarterly reporting because it reduces the burden of an end-of-year crunch to compile twelve months of data. Regardless of the reporting periodicity, the distributor must compile all certifications received during the period to obtain the total quantity that purchasers certified to be for quarantine and preshipment applications. The collection of information on the quantity of methyl bromide sold and certified for quarantine and preshipment applications is needed so that the U.S. can respond to a recent amendment to the Protocol. The amendment, to which the Parties agreed

at their Eleventh Meeting in Beijing in 1999, adds a provision to Article 7 (Reporting of Data), requiring Parties to submit information on the amounts of methyl bromide used for quarantine and preshipment applications. Reporting by the distributors will allow a comparison between the quantities of methyl bromide sold and certified for quarantine and preshipment applications with the amount of methyl bromide produced and imported for quarantine and preshipment applications, as reported in the producers'/importers' report as described in Part VI.A above.

D. What About Reporting of Methyl Bromide Exported for Quarantine and Preshipment Applications?

EPA considered many options for collecting information on the quantity of methyl bromide produced in the U.S. and then exported for quarantine and preshipment applications. With today's action, producers and others that export methyl bromide must report the total quantity of methyl bromide explicitly exported to individual foreign countries for quarantine and preshipment applications on a quarterly basis. Currently, producers and exporters distinguish other exempted quantities of methyl bromide explicitly exported for transformation or destruction. For each export of methyl bromide for quarantine and preshipment applications, as for exports for transformation or destruction, the exporter must obtain a certification from the foreign person (entity) importing the methyl bromide stating that the material will be used only for quarantine and preshipment applications. These certifications must be submitted with the quarterly reports. These certifications will then be shared with the appropriate foreign government officials in the importing country and the compiled data will be shared with UNEP advisory bodies to the Protocol. Certifications must accompany the reporting on quantities exported for quarantine and preshipment applications because of a concern that the U.S., as one of the largest worldwide producers of methyl bromide, could potentially contribute to the creation of a loophole for non-exempt uses of methyl bromide around the globe. EPA feels it will be important to closely monitor and track production of methyl bromide that is exported for quarantine and preshipment applications because these uses are exempt from Protocol control measures.

EPA considered linking periodic reporting on the quantity of methyl bromide exported for quarantine and preshipment applications with a system for refunding allowances. EPA also considered the option of establishing a ceiling on the export of exempted methyl bromide for quarantine and preshipment applications according to historical export levels. EPA considered this option because the U.S. is one of the largest global producers of methyl bromide and EPA is concerned that exempted production of methyl bromide for quarantine and preshipment exports might become a loophole if those exempted quantities were to be used by other Parties for non-quarantine or non-preshipment applications. At this time, EPA has no indication that abuse of the quarantine and preshipment exemption will occur, but the Agency will monitor the situation closely. For development of the final version of the rule, EPA is seeking comments on today's recordkeeping and reporting requirements and other variations for monitoring quantities of methyl bromide produced in the U.S. and exported for quarantine and preshipment applications.

E. Will There Be a FIFRA Pesticide Label Change?

In parallel with today's action, EPA's Office of Pesticide Programs is working with the Methyl Bromide Industry Panel to develop a registration and label change for methyl bromide products under authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The proposed registration/label change under FIFRA would create unique methyl bromide products solely and specifically for quarantine and preshipment applications. A registration/label change would designate individual cylinders of methyl bromide specifically for quarantine and preshipment applications and it would be illegal to use the material in these cylinders for other uses. Under an approved registration/label change there would be unique registration numbers for the new labels that would accompany each cylinder through the chain of commerce from producers or importers to the end-user (the applicator). As currently required under FIFRA, establishments would report total quantities of methyl bromide under this new quarantine and preshipment registration/label to EPA's Office of Pesticide Programs on an annual basis. Following a change in the FIFRA authorized registration/label, as well as today's final action, it will be possible for the Agency to reconcile the total quantity of methyl bromide certified to be solely for quarantine and preshipment applications under procedures described Part VI.B and VI.C above, the total quantity of methyl bromide produced or imported for quarantine and preshipment applications under today's Part VI.A above, and the annual FIFRA establishment reports on methyl bromide, which reference specific products by registration number.

VII. What Are Other Considerations and Situations on Which EPA Is Seeking Comment?

EPA is seeking comments on the following paragraphs that describe possible variations on the exemption that have not been incorporated into today's action and therefore are not effective during the interim period (through December 31, 2002). To assist in developing the final version of the regulation, EPA is seeking comments regarding the items described below. In addition, EPA will consider comments and questions regarding aspects of today's action that are effective for the interim period. If a person has a question about whether a certain aspect of today's interim action applies to their situation, EPA is encouraging the submission of written questions accompanied by a detailed description of how methyl bromide relates to the person's particular enterprise. The Agency will consider questions about whether aspects of today's interim action apply in the context of EPA's regular process for issuing written determinations.

A. What Are Considerations on Which the Agency Is Seeking Comment Regarding Definitions Under the International Plant Protection Convention (IPPC)?

Under the International Standards for Phytosanitary Measures (ISPMs) adopted by members of the International Plant Protection Convention (IPPC) on April 22, 2001, the definition of ''official control'' is different than the definition that was agreed to by the Parties to the Montreal Protocol. The IPPC definition of the phrase ''official control'' is, ''the active enforcement of mandatory phytosanitary regulations and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests or the management of regulated non-quarantine pests.'' The IPPC glossary of phytosanitary terms defines ''official'' as ''established, authorized or performed by a National Plant Protection Organization (NPPO).'' In the United States, the NPPO is the USDA Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ) Program.

Further, under the ISPMs adopted by the IPPC, the phrase ''regulated non-quarantine pests'' is defined as, ''a non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contacting party.'' Because the IPPC definition of ''regulated non-quarantine pest'' refers to ''plants for planting,'' the phytosanitary measure is limited to propagative materials, such as strawberry seedlings. Although the IPPC's definition of ''official control'' includes regulated non-quarantine pests, it should be noted that the Montreal Protocol does not include these regulated non-quarantine pests. In 1998, the TEAP explicitly laid out the differences between the IPPC's and the Montreal Protocol's definitions of ''official control'' for consideration by the Parties. The Parties rejected making any changes to the Protocol's definition of ''official control'' even when presented with the IPPC language. EPA is seeking comments on possible changes to EPA's interpretation of the phrase ''official control'' as used in today's exemption, for purposes of the final rule.

B. What Are considerations on Which the Agency Is Seeking Comment Regarding Prophylactic Fumigation of U.S. Exports When the Fumigation Is Not Mandated by Import Regulations?

U.S. businesses sometimes use methyl bromide against non-quarantine pests for a commodity that is being exported because it is known that the importing country will treat with methyl bromide at the port of entry if the detected level of these non-quarantine pests during port-of-entry inspection exceeds that country's standards. Some U.S. exporters give their commodities a prophylactic treatment in the U.S. to prevent a much more damaging treatment in the receiving country that could occur if non-quarantine pests were found; possibly reducing the quality of the commodity. In cases where an official foreign Party requirement is specific to quarantine pests, or there is a general performance-based quarantine requirement, the use of methyl bromide under the exemption for quarantine applications would be appropriate. In addition, fumigation with methyl bromide to meet U.S. government non-quarantine pest requirements within 21 days prior to export of the commodity would also be exempt under the definition of preshipment applications. However, EPA is seeking comments that would clarify the scope of the prophylactic use of methyl bromide described in this section, where the official foreign Party requirement is *not* specific to quarantine pests.

C. What Are Considerations on Which the Agency Is Seeking Comment Regarding the Exclusion of Specific Quarantine and Preshipment Applications From the Exemption at Some Future Time?

The Parties to the Protocol in Decision XI/13 request Parties to ''review their national plant, animal, environmental, health and stored product regulations with a view to removing the requirement for the use of methyl bromide for quarantine and preshipment where technically and economically feasible alternatives exist.'' The reason for a review process would be to limit the production and import of methyl bromide to only those cases where no other ''technologically and economically feasible alternatives exist.'' Through time, it is likely that the use of methyl bromide will be less and less necessary for quarantine and preshipment applications. When technically and economically feasible alternatives to methyl bromide are available, a process could be devised that would allow the U.S. to limit the use of this ozone-depleting substance while taking into account the need to protect international trade. In the years beyond the methyl bromide production and consumption phaseout, there will continue to be an exemption for quarantine and preshipment applications but there may no longer be price pressures for moving away from these quarantine and preshipment uses of methyl bromide. Therefore, the Parties to the Protocol emphasize the importance of reviewing quarantine and preshipment applications and identifying when technically and economically feasible alternatives exist, and removing these applications from the exemption.

One option for implementing a review process would be to establish a procedure for excluding specific quarantine and preshipment applications from the exemption when EPA determines by notice and comment rulemaking that alternatives are in significant international use for the specific applications. Such a process would allow U.S. users of methyl bromide for quarantine and preshipment applications to make the case that although alternative(s) are in significant international use, the specific circumstances of their U.S. applications are unique (e.g., the alternatives are not feasible or commercially available in the U.S.) and continue to warrant the use of methyl bromide.

Other options for implementing a review process include: (1) Immediately prior to the 2005 methyl bromide phaseout, reviewing and listing all quarantine and preshipment applications that would be exempt beyond the phaseout through notice and comment rulemaking asking for justifications for continued use, (2) eliminating the exemption for quarantine and preshipment applications after the phaseout and asking users to apply for critical-use exemptions where no technically or economically feasible alternatives exist, and (3) conducting periodic reviews (i.e., 3 or 5 years) for listing through notice and comment rulemaking the specific quarantine and preshipment applications that would be exempt because there were no technically or economically feasible alternatives. EPA seeks comments on these and any other potential processes for reviewing the exemption for quarantine and preshipment applications, where technically and economically feasible alternatives exist.

As an alternative to a formal review process, EPA might rely on market prices to guide methyl bromide use. The effectiveness of this price mechanism is to some extent dependent on the behavior of methyl bromide prices over the phasedown period, and particularly on whether a separate market evolves for the pure grade of methyl bromide needed for quarantine and preshipment uses. Basic economic supply and demand principles suggest that the price of methyl bromide is likely to increase during the phaseout period, thereby providing incentives for the development and use of alternatives. Following the phaseout period after January 1, 2005, we expect the price of methyl bromide exempted for quarantine and preshipment applications (and other exemptions that may be established in the future) to likely be determined by the cost of manufacturing those quantities and not by further decreases in supply. We are interested in comments on this view. We are especially interested in comments addressing: (1) The likely behavior of the price of exempt and non-exempt quantities of methyl bromide during the phaseout; (2) the likely behavior of the price of exempt methyl bromide after the phaseout, (3) the impact on these prices of establishing a FIFRA label explicitly for the methyl bromide exempt for quarantine and preshipment applications, (4) the possible impact of

other Federal actions that would influence pricing of methyl bromide, and (5) the value of a price mechanism in assuring that methyl bromide is directed toward those uses where there are no alternatives and/or where it provides the greatest value.

D. What Are Considerations on Which the Agency Is Seeking Comment Regarding National Security Fumigations?

EPA is seeking comments on the possible need for methyl bromide to meet special national security quarantine requirements. The Agency understands that it might be necessary to treat military or other U.S. government property with methyl bromide for import to eliminate possible contamination with biological weapons. EPA is seeking comments on whether a national security quarantine situation could arise that would require a specific exemption. In considering this question, commenters should be aware that prior to the phaseout date some methyl bromide will still be produced without use restrictions, and after the phaseout date, methyl bromide would be available under the emergency use exemption consistent with Decision IX/7 as agreed by the Parties to the Protocol.

VIII. What Are the Steps To Conform the U.S. Methyl Bromide Phaseout Schedule and Exemptions to the Montreal Protocol and the Amended Clean Air Act?

During stakeholder meetings, and in the proposal and final rules that established the 25 percent reduction in methyl bromide baseline allowances beginning in 1999 (64 FR 9290, 64 FR 29240), EPA described its intention to follow with separate rulemakings that would include the additional phaseout steps for methyl bromide and establish additional exemptions in accordance with the Protocol and the CAA. The rule establishing the remaining reduction and phaseout schedule for methyl bromide was published November 28, 2000 (65 FR 70795). The reduction and phaseout schedule is listed above at the end of Part I.

After the phaseout on January 1, 2005, critical-use exemptions are permitted under the Montreal Protocol and the Clean Air Act when nominated by the United States and approved by the Parties. In addition, an emergency use exemption of no more than 20 metric tonnes is available after the phaseout on January 1, 2005. EPA, in consultation with the U.S. Department of Agriculture, is in the process of developing a rulemaking to establish the emergency-use and critical-use exemptions. In 2001, EPA initiated stakeholder meetings to develop rulemaking that will establish the process for an emergency use exemption and the process for critical-use exemptions, which will be designed to ensure the U.S. meets its obligations under the Montreal Protocol consistent with statutory requirements in the Clean Air Act. In 2002, a separate **Federal Register** notice will be published asking for people to submit specific information to substantiate requests for a critical-use exemption. However, at this time no decisions have yet been made regarding what uses will be exempted as ''critical.'' Sometime in advance of 2005, EPA will establish a process for an emergecny use exemption through notice and comment rulemaking.

IX. Administrative Requirements

A. Unfunded Mandates Reform Act

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 explained in the Supplementary Information section of this rulemaking, it is not subject to section 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

B. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

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 explained in the **SUPPLEMENTARY INFORMATION** section of this rulemaking, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*)

C. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines a ''significant'' regulatory action as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector 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 the Executive Order.

Pursuant to the terms of Executive Order 12866, OMB has notified EPA that it considers this a ''significant regulatory action'' within the meaning of the Executive Order. EPA has submitted this action to OMB for review. Changes made in response to OMB suggestions or recommendations on the original rule submitted to them will be documented in the public record.

D. Applicability of E.O. 13045—Children's Health Protection

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This is not such a rule, and therefore E.O. 13045 does not apply.

E. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule for six (6) months under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and the emergency approval provisions of 5 CFR 1320.13. The OMB control number is 2060–0170.

Today's action also serves as the first notice of a request for comment on an extension of today's approval. EPA will follow this action with a second notice in the **Federal Register** regarding

today's information collection. EPA is soliciting comments on specific aspects of the information collection as described below. Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Include the ICR number in any correspondence. Comments must be submitted on or before September 17, 2001. Copies of material supporting this ICR notice are available free of charge from the Stratospheric Ozone Protection Hotline at 1–800–296–1996 between the hours of 10 am and 4 pm Eastern Standard Time or may be received electronically by sending an e-mail to land.tom@epa.gov. For further information contact, Tom Land, U.S. Environmental Protection Agency, Global Programs Division (6205J), 1200 Pennsylvania Ave., NW., Washington, DC 20460, telephone (202)–564–9185, or facsimile (202)–565–2155.

The EPA would like to solicit comments to: (i) 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; (ii) 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; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) 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.

The Office of Management and Budget (OMB) previously approved the information collection requirements contained in the final rule promulgated on August 4, 1998, and assigned OMB control number 2060–0170 (EPA ICR No. 1432.18).

In relation to the expected benefits of today's exemption from the phaseout schedule for methyl bromide, this action is adding additional reporting and recordkeeping requirements. This action increases the information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* This action adds reporting by distributors of methyl bromide regarding the total quantity sold that is certified to be solely for quarantine and preshipment applications. This action also requires applicators of methyl bromide to certify that specified quantities purchased will be used solely for quarantine and preshipment applications. Producers and importers of methyl bromide must include additional information in existing quarterly reports. In addition, producers that export and third-party exporters must submit additional information regarding quantities of methyl bromide exported for quarantine and preshipment applications. Today's action also includes recordkeeping requirements associated with the reporting listed above and an additional recordkeeping requirement for commodity owners or shippers who must formally request methyl bromide use citing the treatment, official control or official requirement for the quarantine and preshipment application.

The information collection under this action is designed to implement the exemption in paragraph 5 under article 2H of the Montreal Protocol for quantities of methyl bromide used for quarantine and preshipment applications as well as the exemption under 604(d)(5) of the CAA. The information collection under this rule is authorized under sections 603(b) and 603(d) of the Clean Air Act Amendments of 1990 (CAA). This information collection is conducted to meet U.S. obligations under Article 7, Reporting Requirements, of the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol); and to carry out the requirements of Title VI of the CAA, including sections 603 and 614.

The reporting requirements included in this rule are intended to:

(1) Allow exempted production and import for a specific exemption and the consequent tracking of that production and import;

(2) Respond to industry comments on the functioning of the program to streamline reporting and eliminate administrative inefficiencies;

(3) Satisfy U.S. obligations under the international treaty, The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol), to report data under Article 7;

(4) Fulfill statutory obligations under Section 603(b) of Title VI of the Clean Air Act Amendments of 1990 (CAA) for reporting and monitoring;

(5) Provide information to report to Congress on the production, use and consumption of class I controlled substances as statutorily required in Section 603(d) of Title VI of the CAA.

EPA informs respondents that they may assert claims of business confidentiality for any of the information they submit. Information claimed confidential will be treated in accordance with the procedures for handling information claimed as confidential under 40 CFR Part 2, Subpart B, and will be disclosed only to the extent, and by means of the procedures, set forth in that subpart. If no claim of confidentiality is asserted when the information is received by EPA, it may be made available to the public without further notice to the respondents (40 CFR 2.203).

The information collection requirements for this action have an estimated reporting burden averaging 1.38 hours per response. This estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing the collection of information.

The estimate includes the time needed to comply with EPA's reporting requirements, as well as that used for the completion of the reports.

Collection activity	No. of respondents	Responses/ respondent	Total responses	Hours per response	Total hours
Producers and Importers Report	4	4	16	1	16
Exporters Report	2	4	8	8	64
Applicator Certification	15	6	90	0.5	45
Distributor Report	15	1	15	16	240
Commodity Owner, Shipper or Agent Recordkeeping	500	10	500	1	500

Collection activity	No. of respondents	Responses/ respondent	Total responses	Hours per response	Total hours
Total Burden Hrs					865

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

F. Executive Order 13132 (Federalism):

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.''

Under Section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the regulation.

This rule does not have federalism implications. 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. This rule does not in any way restrict States from continuing to operate their plant, animal, environmental, health or stored product protection programs associated with quarantine and preshipment applications. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

On January 1, 2001, EO 13084 was superseded by EO 13175. However, this rule was developed during the period when EO 13084 was still in force, and so tribal considerations were addressed under EO 13084. Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies or matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. The rule does not impose any enforceable duties on communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

H. The National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, § 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rulemaking does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

I. Executive Order 13211 (Energy Effects)

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Further, we have concluded that this rule is not likely to have any adverse energy effects.

X. Congressional Review

A. Submission to Congress and the Comptroller General

The Congressional Review Act, 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. 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective July 19, 2001.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Exports, Imports, Methyl Bromide, Quarantine, Preshipment, Ozone layer.

Dated: July 11, 2001.

Christine Todd Whitman,

Administrator.

For reasons set out in the preamble, title 40 chapter I of the Code of Federal Regulations is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for subpart 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart A—Production and Consumption Controls

2. Section 82.3 is amended by adding new definitions in alphabetical order for the terms, ''Applicator'', ''Commodity owner, shipper or their agent'', ''Distributor of methyl bromide'', ''Preshipment applications'', and ''Quarantine applications''.

§ 82.3 Definitions.

As used in this subpart, the term:

Applicator means the person who applies methyl bromide.

* * * * *

Commodity owner, shipper or their agent means the person requesting that an applicator use methyl bromide for quarantine or preshipment applications.

* * * * *

Distributor of methyl bromide means the person directly selling a class I, Group VI controlled substance to an applicator.

* * * * *

Preshipment applications, with respect to class I, Group VI controlled substances, are those non-quarantine applications applied within 21 days prior to export to meet the official requirements of the importing country or existing official requirements of the exporting country. Official requirements are those which are performed by, or authorized by, a national plant, animal, environmental, health or stored product authority.

* * * * *

Quarantine applications, with respect to class I, Group VI controlled substances, are treatments to prevent the introduction, establishment and/or spread of quarantine pests (including diseases), or to ensure their official control, where:

(1) Official control is that performed by, or authorized by, a national plant, animal or environmental protection or health authority;

(2) Quarantine pests are pests of potential importance to the areas endangered thereby and not yet present there, or present but not widely distributed and being officially controlled.

* * * * *

3. Section 82.4 is amended by redesignating paragraph (a) as (a)(1) and republishing the text, adding paragraph (a)(2), redesignating paragraph (c) as (c)(1) and republishing the text, adding paragraph (c)(2), redesignating paragraph (k) as (k)(1) and republishing the text, and adding paragraph (k)(2) as follows:

§ 82.4 Prohibitions.

(a)(1) Prior to January 1, 1996, for all Groups of class I controlled substances, and prior to January 1, 2005, for class I, Group VI controlled substances, no person may produce, at any time in any control period, (except that are transformed or destroyed domestically or by a person of another Party) in excess of the amount of unexpended production allowances or unexpended Article 5 allowances for that substance held by that person under the authority of this subpart at that time for that control period. Every kilogram of excess production constitutes a separate violation of this subpart.

(2) From January 1, 2001 through December 31, 2002, production of class I, Group VI controlled substances is not subject to the prohibitions in paragraph (a)(1) of this section if it is solely for quarantine or preshipment applications as defined in this Subpart.

* * * * *

(c)(1) Prior to January 1, 1996, for all Groups of class I controlled substances, and prior to January 1, 2005, for class I, Group VI controlled substances, no person may produce or (except for transhipments, heels or used controlled substances) import, at any time in any control period, (except for controlled substances that are transformed or destroyed) in excess of the amount of unexpended consumption allowances held by that person under the authority of this subpart at that time for that control period. Every kilogram of excess production or importation (other than transhipments, heels or used controlled substances) constitutes a separate violation of this subpart.

(2) From January 1, 2001 through December 31, 2002, production and import of class I, Group VI controlled substances is not subject to the prohibitions in paragraph (c)(1) of this section if it is solely for quarantine or preshipment applications as defined in this Subpart.

* * * * *

(k)(1) Prior to January 1, 1996, for all Groups of class I controlled substances, and prior to January 1, 2005, for class I, Group VI controlled substances, a person may not use production allowances to produce a quantity of a class I controlled substance unless that person holds under the authority of this subpart at the same time consumption allowances sufficient to cover that quantity of class I controlled substances nor may a person use consumption allowances to produce a quantity of class I controlled substances unless the person holds under authority of this subpart at the same time production allowances sufficient to cover that quantity of class I controlled substances. However, prior to January 1, 1996, for all class I controlled substances, and prior to January 1, 2005, for class I, Group VI controlled substances, only consumption allowances are required to import, with the exception of transhipments, heels, used controlled substances. Effective January 1, 1996, for all Groups of class I controlled substances, except Group VI, only essential-use allowances or exemptions are required to import class I controlled substances, with the exception of transhipments, heels and used controlled substances.

(2) Notwithstanding paragraph (k)(1) of this section, from January 1, 2001 through December 31, 2002, for class I, Group VI controlled substances, consumption allowances are not required to import quantities solely for quarantine or preshipment applications as defined in this Subpart.

* * * * *

4. Section 82.13 is amended by:

a. Adding paragraphs (f)(2)(xvii) through (f)(2)(xix), and (f)(3)(xiii) through (f)(3)(xv),

b. Adding paragraphs (g)(1)(xvii) through (g)(1)(xix), and (g)(4)(xv) through (g)(4)(xvii),

c. Revising paragraph (h),

(d). Adding paragraphs (aa), (bb), and (cc).

The revisions and additions read as follows:

§ 82.13 Recordkeeping and reporting requirements.

* * * * *

(f) * * *

(2) * * *

(xvii) For class I, Group VI controlled substances, dated records of the quantity of controlled substances produced for quarantine and preshipment applications and quantity sold for quarantine and preshipment applications;

(xviii) Written certifications that quantities of class I, Group VI controlled substances produced solely for quarantine and preshipment applications were purchased by distributors or applicators to be used only for quarantine and preshipment applications in accordance with the definitions in this Subpart; and

(xix) Written verifications from a U.S. purchaser that class I, Group VI controlled substances produced solely for quarantine and preshipment applications, if exported, will be exported solely for quarantine and preshipment applications upon receipt of a certification in accordance with the definitions of this Subpart and requirements in paragraph (h) of this section.

(3) * * *

(xiii) The amount of class I, Group VI controlled substances sold or transferred during the quarter to a person other than the producer solely for quarantine and preshipment applications;

(xiv) A list of the quantities of class I, Group VI controlled substance produced by the producer and exported by the producer and/or by other U.S. companies, to a Party to the Protocol that will be used solely for quarantine and preshipment applications and therefore were not produced expending production or consumption allowances; and

(xv) For quarantine and preshipment applications of class I, Group VI controlled substances in the United States or by a person of another Party, one copy of a certification that the material will be used only for quarantine and preshipment applications in accordance with the definitions in this Subpart from each recipient of the material and a list of additional quantities shipped to that same person for the quarter.

* * * * *

(g) * * *

(1) * * *

(xvii) For class I, Group VI controlled substances, dated records of the quantity of controlled substances imported for quarantine and preshipment applications and quantity sold for quarantine and preshipment applications;

(xviii) Written certifications that quantities of class I, Group VI controlled substances imported solely for quarantine and preshipment applications were purchased by distributors or applicators to be used only for quarantine and preshipment applications in accordance with the definitions in this Subpart; and

(xix) Written verifications from a U.S. purchaser that class I, Group VI controlled substances imported solely for quarantine and preshipment applications, if exported, will be exported solely for quarantine and preshipment applications upon receipt of a certification in accordance with the definitions of this Subpart and requirements in paragraph (h) of this section.

* * * * *

(4) * * *

(xv) The amount of class I, Group VI controlled substance sold or transferred during the quarter to a person other than the importer solely for quarantine and preshipment applications;

(xvi) A list of the quantities of class I, Group VI controlled substance exported by the importer and or by other U.S. companies, to a Party to the Protocol that will be used solely for quarantine and preshipment applications and therefore were not imported expending consumption allowances; and

(xvii) For quarantine and preshipment applications of class I, Group VI controlled substances in the United States or by a person of another Party, one copy of a certification that the material will be used only for quarantine and preshipment applications in accordance with the definitions in this Subpart from each recipient of the material and a list of additional quantities shipped to that same person for the quarter.

(h) *Reporting Requirements—Exporters.*

(1) For any exports of class I controlled substances (except Group VI) not reported under § 82.10 of this subpart (additional consumption allowances), or under paragraph (f)(3) of this section (reporting for producers of controlled substances), the exporter who exported a class I controlled substance (except Group VI) must submit to the Administrator the following information within 45 days after the end of the control period in which the unreported exports left the United States:

(i) The names and addresses of the exporter and the recipient of the exports;

(ii) The exporter's Employee Identification Number;

(iii) The type and quantity of each controlled substance exported and what percentage, if any, of the controlled substance is used, recycled or reclaimed;

(iv) The date on which, and the port from which, the controlled substances were exported from the United States or its territories;

(v) The country to which the controlled substances were exported;

(vi) The amount exported to each Article 5 country;

(vii) The commodity code of the controlled substance shipped; and

(viii) The invoice or sales agreement containing language similar to the Internal Revenue Service Certificate that the purchaser or recipient of imported controlled substances intends to transform those substances, or destruction verifications (as in paragraph(k) of this section) showing that the purchaser or recipient intends to destroy the controlled substances.

(2) For any exports of class I, Group VI controlled substances not reported under § 82.10 of this subpart (additional consumption allowances), or under paragraph (f)(3) of this section (reporting for producers of controlled substances), the exporter who exported a class I, Group VI controlled substance must submit to the Administrator the following information within 45 days after the end of each quarter in which the unreported exports left the United States:

(i) The names and addresses of the exporter and the recipient of the exports;

(ii) The exporter's Employee Identification Number;

(iii) The type and quantity of each controlled substance exported and what percentage, if any, of the controlled substance is used, recycled or reclaimed;

(iv) The date on which, and the port from which, the controlled substances were exported from the United States or its territories;

(v) The country to which the controlled substances were exported;

(vi) The amount exported to each Article 5 country;

(vii) The commodity code of the controlled substance shipped; and

(viii) The invoice or sales agreement containing language similar to the Internal Revenue Service Certificate that the purchaser or recipient of imported controlled substances intends to transform those substances, the

destruction verifications (as in paragraph (k) of this section) showing that the purchaser or recipient intends to destroy the controlled substances, or the certification that the purchaser or recipient and the eventual applicator will only use the material for quarantine and preshipment applications in accordance with the definitions in this Subpart.

* * * * *

(aa) Every distributor of methyl bromide (class I, Group VI controlled substances) who purchases or receives a quantity produced or imported solely for quarantine or preshipment applications under the exemptions in this Subpart must comply with recordkeeping and reporting requirements specified in this paragraph (aa) of this section.

(1) Every distributor of methyl bromide must certify to the producer or importer that quantities received that were produced or imported solely for quarantine and preshipment applications under the exemptions in this Subpart will be used only for quarantine applications or preshipment applications in accordance with the definitions in this Subpart.

(2) Every distributor of a quantity of methyl bromide that was produced or imported solely for quarantine or preshipment applications under the exemptions in this Subpart must receive from an applicator a certification of the quantity of class I, Group VI controlled substances ordered, prior to delivery of the quantity, stating that the quantity will be used solely for quarantine or preshipment applications in accordance with definitions in this Subpart.

(3) Every distributor of methyl bromide who receives a certification from an applicator that the quantity ordered and delivered will be used solely for quarantine and preshipment applications in accordance with definitions in this Subpart must maintain the certifications as records for 3 years.

(4) Every distributor of methyl bromide who receives a certification from an applicator that the quantity ordered and delivered will be used solely for quarantine and preshipment applications in accordance with definitions in this Subpart must report to the Administrator within 45 days after the end of the control period, the total quantity delivered for which certifications were received that stated the class I, Group VI controlled substance would be used solely for quarantine and preshipment applications in accordance with definitions in this Subpart.

(bb) Every applicator of class I, Group VI controlled substances who purchases or receives a quantity produced or imported solely for quarantine and preshipment applications under the exemptions in this Subpart must comply with recordkeeping and reporting requirements specified in this paragraph (bb) of this section.

(1) Recordkeeping—Applicators. Every applicator of class I, Group VI controlled substances produced or imported solely for quarantine and preshipment applications under the exemptions of this Subpart must maintain, for every application, a document from the commodity owner, shipper or their agent requesting the use of class I, Group VI controlled substances citing the regulatory requirement that justifies its use in accordance with definitions in this Subpart. These documents shall be retained for 3 years.

(2) Reporting—Applicators. Every applicator of class I, Group VI controlled substances who purchases or receives a quantity of class I, Group VI controlled substance that was produced or imported solely for quarantine and preshipment applications under the exemptions in this Subpart shall provide the distributor of the methyl bromide, prior to shipment of the class I, Group VI controlled substance, with a certification that the quantity of controlled substances will be used only for quarantine and preshipment applications as defined in this Subpart.

(cc) Every commodity owner, shipper or their agent requesting an applicator to use a quantity of class I, Group VI controlled substance that was produced or imported solely for quarantine and preshipment applications under the exemptions of this Subpart must maintain a record for 3 years, for each request, certifying knowledge of the requirements associated with the exemption for quarantine and preshipment applications in this Subpart and citing the regulatory requirement that justifies the use of the class I, Group VI controlled substance in accordance with definitions in this Subpart.

[FR Doc. 01–17907 Filed 7–18–01; 8:45 am]

BILLING CODE 6560–50–P

Federal Register

Thursday,
July 19, 2001

Part IV

Environmental Protection Agency

40 CFR Parts 152 and 174

Plant-Incorporated Protectants; Final Rules and Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152 and 174

[OPP–300369B; FRL–6057–7]

RIN 2070–AC02

Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The substances plants produce for protection against pests, and the genetic material necessary to produce these substances, are pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if humans intend to use these substances for ''preventing, repelling or mitigating any pest.'' In this rule, EPA finalizes certain of the proposed rules published in 1994, 1996, and 1997. Specifically, EPA changes the name of this type of pesticide from ''plant-pesticide'' to ''plant-incorporated protectant''; clarifies the relationship between plants and plant-incorporated protectants under FIFRA; exempts from FIFRA requirements plant-incorporated protectants derived through conventional breeding from sexually compatible plants; and establishes a new part in the Code of Federal Regulations (CFR) specifically for plant-incorporated protectants. Procedures are also set forth for Confidential Business Information (CBI); any claim of confidentiality must be substantiated when the claim is made. This rule will benefit the public by ensuring that public health and the environment are adequately protected while reducing burden on the regulated community, thereby potentially reducing costs for consumers.

DATES: This rule is effective September 17, 2001.

FOR FURTHER INFORMATION CONTACT: Philip Hutton, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8260; e-mail address: hutton.phil@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a person or company involved with agricultural biotechnology that may develop and market plant-incorporated protectants. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Pesticide manufacturers	32532	Establishments primarily engaged in the formulation and preparation of agricultural and household pest control chemicals
Seed companies	111	Establishments primarily engaged in growing crops, plants, vines, or trees and their seeds
Colleges, universities, and professional schools	611310	Establishments of higher learning which are engaged in development and marketing of plant-incorporated protectants
Establishments involved in research and development in the life sciences	54171	Establishments primarily engaged in conducting research in the physical, engineering, or life sciences, such as agriculture and biotechnology

This table is not intended to be exhaustive, but rather provides a guide for readers regarding the types of entities potentially affected by this action. Other types of entities not listed in the table 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 provisions in 40 CFR part 174. If you have any questions regarding applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'', ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. To access information about EPA's program for biopesticides go directly to the Home Page for the Office of Pesticide Programs at http://www.epa.gov/pesticides/biopesticides.

2. *In person.* The Agency has established an official record for this action under the docket control number OPP–300369B. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Record Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Under What Authority Is EPA Issuing The Rule?

A. FIFRA

This rule is promulgated under the authority of FIFRA section 3 and section 25(a) and (b) (7 U.S.C. 136a and 136w(a) and (b)) and FFDCA section 346a and 371.

FIFRA section 3(a) provides, with some exceptions, that no person may distribute or sell in the United States any pesticide that is not registered

under the Act (7 U.S.C. 136a(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'' with certain exceptions (7 U.S.C. 136(t)).

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, or subject to an experimental use permit under section 5 of FIFRA, or subject to an emergency exemption under section 18 of FIFRA (7 U.S.C. 136a(a)). Pesticides that are ''not registered'' include pesticides that are exempt from FIFRA requirements under section 25(b).

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 adverse effects on the environment'' (7 U.S.C. 136a(c)(5)). 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)).

When EPA published its proposed rules and policy for plant-incorporated protectants in 1994, the FIFRA definition of ''unreasonable adverse effects'' contained only the first criterion of unreasonable risk to man or the environment. Subsequently, Congress enacted the Food Quality Protection Act (FQPA) in 1996, and expanded the FIFRA definition of ''unreasonable adverse effects on the environment'' by adding the second criterion of consistency with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (Public Law 104–170 (August 3, 1996)). As a result of this change, a pesticide must meet both criteria of the unreasonable adverse effects test to qualify for registration. In the case of a pesticide whose use would not result in residues in or on food, the second criterion would not apply. Once a pesticide has been registered, it may be sold and distributed in the United States.

Section 25(b)(2) of FIFRA allows EPA to exempt, by regulation, any pesticide from some or all of the requirements of FIFRA, if the pesticide is of a character which is unnecessary to be subject to FIFRA in order to carry out the purposes of that Act (7 U.S.C. 136w(b)(2)). EPA interprets FIFRA section 25(b)(2) to authorize EPA to exempt a pesticide or category of pesticides that EPA determines poses a low probability of risk to the environment, and that is not likely to cause unreasonable adverse effects to the environment even in the absence of regulatory oversight under FIFRA.

To determine whether a pesticide qualifies for an exemption under section 25(b)(2), EPA evaluates both the potential risks and benefits of the use of the pesticide. In evaluating a pesticide under the first exemption criterion, 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.B. EPA will not exempt pesticides under section 25(b)(2) that fail the low probability of risk criterion.

In evaluating a pesticide under the second exemption criterion, whether the use of the pesticide is likely 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 any dietary risks (see Unit II.B. for a discussion of the relationship between this finding and section 408 of the FFDCA), 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 meets both exemption criteria, EPA may exempt the pesticide from regulation under FIFRA section 25(b)(2).

B. Relationship of FIFRA Exemptions to the FFDCA Section 408 Standard

Under FFDCA section 408(a), a pesticide chemical residue in or on food is not safe unless EPA has issued either: A tolerance for the residue and the residue is within the tolerance limits, or 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 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)). 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 exemptions from the FFDCA requirement of a tolerance published elsewhere in this issue of the **Federal Register** (i.e., exemptions for residues of plant-incorporated protectants derived through conventional breeding from a plant sexually compatible with the recipient plant, and residues of nucleic acids that are part of a plant-incorporated protectant).

EPA uses the FFDCA section 408 safety standard in evaluating whether a pesticide used in food meets the two FIFRA exemption criteria with respect to human dietary risk. A pesticide in food qualifies under the first FIFRA exemption criterion of 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 meets the second FIFRA exemption criterion of no likely unreasonable adverse effects, with respect to human dietary risks only, if the risks resulting from use of that pesticide are consistent with the FFDCA section 408 exemption standard, and the potential benefits of use outweigh any human health risk even in the absence of regulatory oversight.

A determination that a pesticide chemical meets the safety standard of section 408(c) of the FFDCA may also be relevant to whether a pesticide qualifies for a FIFRA section 25(b)(2) exemption with respect to human health risks arising from other routes of exposure. In

determining whether a pesticide chemical residue is safe, EPA must consider ''available information regarding the aggregate exposure levels of consumers . . . to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposures from other non-occupational sources.'' (21 U.S.C. section 346a(b)(2)(D)(vi)). Consequently, a finding that a pesticide qualifies for a tolerance exemption could also demonstrate that the pesticide chemical meets the first exemption criterion of low probability of risk with respect to human health risks arising from other non-occupational routes of exposure. Such a pesticide also meets the second FIFRA exemption criterion of no likely unreasonable adverse effects, with respect to human health risks arising from all non-occupational exposures, if the risks resulting from use of that pesticide are consistent with the FFDCA section 408 exemption standard, and the potential benefits of use outweigh any human health risk even in the absence of regulatory oversight.

However, FIFRA does not provide for exemption of a pesticide in food based solely upon consistency with the FFDCA section 408 exemption standard. At a minimum, EPA also must evaluate risks arising from occupational exposure to humans and determine that such risks meet both exemption criteria. In addition, EPA must evaluate the risks to the environment from the pesticide and determine both that the pesticide poses only a low probability of environmental risks, and that use of the pesticide is not likely to cause any unreasonable adverse effects on the remainder of the environment in the absence of regulation under FIFRA.

III. What is the Background for this Rule?

This final rule establishes certain basic parameters of EPA's regulatory program under FIFRA for plant-incorporated protectants. In this rule, EPA defines the scope of products subject to FIFRA jurisdiction, and identifies the category of products over which it will exert regulatory oversight. EPA also establishes certain fundamental definitions to clarify what will be subject to regulation as a plant-incorporated protectant. The rule also finalizes certain regulatory procedures specific to plant-incorporated protectants. This document also provides some guidance on the way in which the Agency intends to interpret the existing regulations for these products until it is able to establish additional regulations specific to plant-incorporated protectants.

Specifically, the rule clarifies that plants used as biological control agents remain exempt from FIFRA requirements, but that plant-incorporated protectants are not. Second, the rule exempts plant-incorporated protectants derived through conventional breeding from sexually compatible plants. Third, this final rule establishes a new 40 CFR part 174, specifically for plant-incorporated protectants; any additional regulations specific to plant-incorporated protectants will be codified in 40 CFR part 174. The final rule also imposes a requirement at § 174.71, that any person producing an otherwise exempt plant-incorporated protectant for sale and distribution, who obtains any information regarding adverse effects of this otherwise exempt plant-incorporated protectant on human health or the environment report that information to EPA. Finally, the rule includes a provision that any claim of confidentiality must be made at the time of submission and substantiated at the time the claim is made.

A. What Is a Plant-Incorporated Protectant?

Plants have evolved, and thus naturally possess, various mechanisms to resist pests. The mechanisms of resistance can be varied, including, for example, structural characteristics of the plant, the production of metabolites that have toxic properties, biochemical cascades resulting in localized necrosis of plant tissue, or the production of specific toxic substances in response to pest attack. Humans have for approximately 10,000 years selected and bred certain plants as sources of, for example, food, feed, and fiber, and a frequently selected characteristic was the ability to resist pests. More recently, humans have developed scientific techniques by which traits from any living organism, including an ability to resist pests, can be introduced into a plant. When humans intend to use substances involved in these mechanisms in plants for ''preventing, destroying, repelling or mitigating any pest,'' the substances are pesticides under the FIFRA definition of pesticide, regardless of whether the pesticidal capability evolved in the plants or was introduced by breeding or through the techniques of modern biotechnology.

The genetic material necessary for the production of such a pesticidal substance also meets the FIFRA statutory definition of a pesticide. Such genetic material is introduced into a plant with the intent of ultimately producing a pesticidal effect even though the genetic material may not, itself, directly affect pests. The pesticidal substance, along with the genetic material necessary to produce it, produced and used in living plants, is designated a ''plant-incorporated protectant'' by EPA.

Plant-incorporated protectants are primarily distinguished from other types of pesticides because they are intended to be produced and used in the living plant. This difference in use pattern dictates in some instances differences in approach. For example, because the plant-incorporated protectant is produced by the plant itself and used in the living plant, exposure considerations in risk assessments may be different, although as noted in Unit VII.D.2., the risk assessment framework used for other types of pesticides can be used for plant-incorporated protectants.

B. Does the Rule Have Any Relevance to Other Types of Pesticides?

Nonviable plant tissues, organs, or parts that are used as pesticides, will not be subject to the provisions of this rule, which will be codified in regulations at 40 CFR part 174. Rather, such pesticides are subject to the regulations found in 40 CFR parts 150 through 173 and 40 CFR parts 177 through 180. An example of this type of pesticide would be the powder, produced by drying and grinding cayenne peppers, dusted on plants to protect them from pests.

Substances that are isolated from a plant's tissues and then applied to plants for pest control will not be subject to the regulations in 40 CFR part 174. Rather these types of pesticides in formulations such as those for foliar application are subject to regulations found in 40 CFR parts 150 through 173 and 40 CFR parts 177 through 180. An example of this type of pesticide would be pyrethrum isolated from chrysanthemum plants, formulated with other ingredients for foliar application, and sprayed on other plants for pest control.

Substances that are synthesized will not be subject to the regulations in 40 CFR part 174. Such pesticides are subject to regulations found in 40 CFR parts 150 through 173 and 40 CFR parts 177 through 180. An example of this type of pesticide is the herbicide, atrazine.

C. What is the History of this Rule?

This rule is an additional step in fully implementing the ''Coordinated Framework for Regulation of

Biotechnology'' of the United States of America which was published in the **Federal Register** by the Office of Science and Technology Policy (OSTP) on June 26, 1986 (51 FR 23302).

EPA sponsored, or cosponsored with other Federal agencies, three conferences dealing with plant related issues: On October 19–21, 1987, a meeting on ''Genetically Engineered Plants: Regulatory Considerations'' at Cornell University, 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. Information from these conferences has been incorporated as appropriate in development of this rule.

In developing its approach to plant-incorporated protectants, EPA requested advice from two scientific advisory groups at three meetings. On December 18, 1992, a Subpanel of the FIFRA Scientific Advisory Panel (SAP) was convened to review a draft proposed policy statement and to answer a series of scientific questions concerned primarily with EPA's proposed exemptions under FIFRA. On July 13, 1993, a Subcommittee of the EPA Biotechnology Science Advisory Committee (BSAC) was convened to address a series of scientific questions concerned primarily with EPA's proposed exemptions under the FFDCA. On January 21, 1994, a joint meeting of the Subpanel of the SAP and the BSAC Subcommittee was convened to address a series of scientific questions on approaches to plant-pesticides under both FIFRA and FFDCA. Advice from these scientific advisory groups was considered in finalizing this rule.

EPA published in the November 23, 1994, **Federal Register** a package of five separate documents (59 FR 60496, 60519, 60535, 60542 and 60545) (FRL–4755–2, FRL–4755–3, FRL–4755–4, and FRL–4755–8) which described EPA's policy and proposals for plant-pesticides (now called plant-incorporated protectants) under FIFRA and FFDCA. On July 22, 1996, EPA published a supplemental document in the **Federal Register** (61 FR 37891) (FRL–5387–4) on one aspect of its November 23, 1994, **Federal Register** documents; i.e., how the concept of inert ingredient related to plant-pesticides.

In August of 1996, Congress enacted the FQPA which amended FFDCA and FIFRA. On May 16, 1997, EPA published in the **Federal Register** supplemental documents (62 FR 27132, 27142, 27149) (FRL–5716–6, FRL–5716–7, FRL–5717–2) 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 exemptions from the FFDCA requirement of a tolerance for two categories of residues relevant to this final rule.

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 this type of pesticide.

The documents and reports of the meetings described in this unit are available in the official record for this rule as described in Unit VIII.

D. Other Federal Agencies

EPA is the Federal agency primarily responsible for the regulation ofpesticides. In fulfilling this mission, 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 the 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 for Regulation of Biotechnology (51 FR 23302, June 26, 1986); 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. It is also more likely to conserve resources as submitters would more likely be able to use data developed for one agency to meet requirements posed by another agency for the same or similar products.

1. *USDA*. USDA has authority to prevent the introduction and dissemination of plant pests under the PPA. Before introducing into the environment a plant that is regulated under either of these statutes, approval must be obtained from the USDA/Animal Plant Health Inspection Service (APHIS) unless the plant is exempt from USDA/APHIS regulation. The USDA regulations use genetic engineering as a criterion for determining the scope of its regulations (Refs. 1, 2, and 3).

EPA recognizes that there is a potential for duplicative oversight with respect to certain issues that may arise in plant-incorporated protectant decisions. For example, some of the plant-incorporated protectants not exempted by EPA are also subject to APHIS/USDA requirements under the PPA. The potential for most plants containing plant-incorporated protectants to pose weediness concerns is directly considered by USDA/APHIS under PPA. 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 when reviews of any plant-incorporated protectant indicates reason for concern over any of these issues. Weediness is generally thought to be due to a multiplicity of factors. The Agencies will work to coordinate their analyses of these factors in accordance with their respective expertise and jurisdiction. EPA's focus in considering these issues is on the statutory determination on unreasonable adverse effects the Agency must make with respect to pesticides, rather than on the engineered plant itself. In particular, these plant-related issues may potentially impact use patterns of pesticides, which are of relevance to the Agency. EPA and USDA/APHIS will work together to avoid potential duplication and inconsistencies.

2. *FDA*. FDA is the primary U.S. agency responsible forensuring 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 FFDCA and the reorganization that created EPA, pesticides as defined by FIFRA are subject to EPA's regulatory authority under FFDCA. Recently, FDA announced its intent to propose a pre-market notification scheme for foods derived from plants modified through the use of modern biotechnology.

IV. What Are the Key Features of the Proposed Rule?

The development of this rule consists of a proposed rule that appeared in the November 23, 1994, **Federal Register** and four supplemental documents affecting the final form of the rule (59 FR 60496, 60519, 60535, 60542, and 60545); a supplemental document that appeared in the July 22, 1996, **Federal Register** (61 FR 37891), two supplemental documents that appeared in the May 16, 1997, **Federal Register** (62 FR 27132, 27142), and a supplemental document that appeared in the April 23, 1999, **Federal Register** (64 FR 19958).

A. What Are the Key Features of the November 23, 1994, **Federal Register***?*

In the November 23, 1994, **Federal Register** document (59 FR 60519), EPA proposed to: first, clarify how the exemption at 40 CFR 152.20 relates to plants used as biological control agents and to plant-incorporated protectants; second, exempt under FIFRA section 25(b)(2), plant-incorporated protectants that are derived from plants closely related to the recipient plant, except for a requirement that sellers or distributors of an otherwise exempt plant-incorporated protectant submit to EPA any information they may obtain regarding potential unreasonable adverse effects caused by an exempt plant-incorporated protectant; and third, establish new part 40 CFR part 174 specifically for plant-incorporated protectants. This document also contained a proposed rule on substantiation of any claim of confidentiality at the time the claim was made.

1. *Clarification of exemption at 40 CFR 152.20; status of plants used as biological control agents with regard to FIFRA requirements.* In the November 23, 1994, **Federal Register** document, EPA proposed to amend 40 CFR 152.20 to clarify that plants used as biological control agents are exempt from FIFRA requirements under section 25(b)(1). The proposed amendment at 40 CFR 152.20 would also indicate that this exemption does not apply to plant-incorporated protectants and would refer the reader to 40 CFR part 174 for regulations, including a listing of exemptions, on plant-incorporated protectants.

2. *Proposed exemption of plant-incorporated protectants derived from plants closely related to the recipient plant.* In 1994, EPA described three options for defining when a plant-incorporated protectant would be exempt because it is derived from plants closely related to the recipient plant. EPA proposed to exempt plant-incorporated protectants derived from plants closely related to the recipient plant based on the rationale that the probability of new exposures from this group of plant-incorporated protectants is very low. Option 1, the Agency's preferred option, used sexual compatibility, including hybridization achieved by wide and bridging crosses, as a measure of relatedness between plants. Under this option, plant-incorporated protectants would be exempt from all FIFRA requirements, except for the adverse effects reporting requirement, if the genetic material that leads to the production of the pesticidal substance is derived from plants that are sexually compatible with the recipient plant and has never been derived from a source that is not sexually compatible with the recipient plant. Recipient plant was described as the plant into which the plant-incorporated protectant is introduced and in which the plant-incorporated protectant is produced. Sexually compatible, when referring to plants, was described as capable of forming a viable zygote through the fusion of two gametes including the use of bridging or wide crosses between plants.

Option 2 would utilize the rank of genus as the taxonomic standard for describing closely related plants such that plant-incorporated protectants derived from plants classified in the same genus as the recipient plant would be exempt from all FIFRA requirements, except for the adverse effects reporting requirement. Taxonomy is a system of orderly classification of organisms according to their presumed natural relationships. Taxonomy reflects current scientific observations about phenotypic, and to a certain extent, genotypic, similarities between organisms.

Option 3, also an alternative option, would utilize both the taxonomic rank of genus and sexual compatibility to describe closely related plants. This option would exempt from all FIFRA requirements, except for the adverse effects reporting requirement, plant-incorporated protectants derived from plants classified in the same genus as the recipient plant, as well as plant-incorporated protectants derived from plants sexually compatible with the recipient plant. Under Options 1 and 3, plant-incorporated protectants derived from plants sexually compatible with the recipient plant would be exempt even if the source and recipient plants are classified in different genera.

None of the options offered by the EPA were intended to exempt a plant-incorporated protectant that has been modified so that it is significantly different functionally from the plant-incorporated protectant as it occurs in the source organism (59 FR 60524).

i. *Associated definitions.* In 1994, pertinent definitions associated with the proposed exemptions included:

''Bridging crosses between plants'' would be the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.

''Wide crosses between plants'' would be to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre-pollination and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures, or any other technique that the Administrator determines meets this definition.

In 1994, EPA also presented a definition for plant-pesticide, now termed plant-incorporated protectant, and definitions of active and inert ingredient for plant-pesticides.

''Plant-pesticide'' was defined as a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

''Active ingredient,'' when referring to plant-incorporated protectants only, was defined as a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

''Genetic material necessary for the production'' was defined as: Genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance and regulatory regions. It does not include noncoding, nonexpressed nucleotide sequences.

''Inert ingredient,'' when referring to plant-incorporated protectants only, was defined as any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient.

''Living plant'' was defined as a plant that is alive, including periods of dormancy, and all viable plant parts/organs involved in the plant's life cycle.

''Noncoding, nonexpressed nucleotide sequences'' were defined as the nucleotide sequences that are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

ii. *Potential exemption criterion based on process.* The Agency also requested

in the 1994 **Federal Register** document (50 FR 60514, 60530), comment on the utility of an exemption criterion based on the process (e.g., rDNA) used to introduce the plant-incorporated protectant into a plant. In this approach, plant-incorporated protectants developed through techniques other than those of modern biotechnology would be exempted, e.g., those developed through conventional plant breeding would be exempted. Categories of those plant-incorporated protectants that were not exempted could subsequently be considered for exemption on the basis of risk potential.

iii. *Reporting of unreasonable adverse effects for exempted plant-incorporated protectants*. In 1994, EPA proposed to require, under FIFRA section 3(a), that any person who sells or distributes any otherwise exempt plant-incorporated protectant, who obtains any information regarding potential unreasonable adverse effects on human health or the environment, must within 30 days of receipt of such information submit the information to EPA. This provision was proposed to enable the Agency to address unforeseeable events from use of otherwise exempt plant-incorporated protectants. (This reporting requirement is referred to, in this preamble, as the ''adverse effects reporting requirement.'')

3. *Proposed new 40 CFR part 174*. In the November 23, 1994, **Federal Register** document, EPA proposed to establish a new part in the CFR, 40 CFR part 174, specifically for plant-incorporated protectants. Establishment of a new part would allow the Agency to consolidate regulations specifically applicable to plant-incorporated protectants in one part of the CFR. EPA believed such a consolidation would be appropriate and justified because of the characteristics that distinguish plant-incorporated protectants from other types of pesticides. The proposed consolidation was expected to benefit the public by providing greater focus, enhanced clarity, and ease of use, because all the regulations specific for plant-incorporated protectants would be in one part of title 40. The proposed 40 CFR part 174 would include, for example, definitions that are generally applicable throughout part 174, exemptions from FIFRA regulation, and a subpart for tolerances and exemptions from the requirement of a tolerance published under FFDCA section 408 for residues of plant-incorporated protectants.

4. *Proposed rule regarding upfront substantiation of confidential business information*. EPA proposed in 1994 that any claim of confidentiality would have to be made at the time of submission and substantiated at the time the claim is made.

B. What Issues Were Discussed in the Supplemental **Federal Register** *Documents?*

Subsequent to publication of the November 23, 1994 **Federal Register** document (59 FR 60519), EPA published four supplemental documents relevant to this document. These supplemental documents are described below.

1. *July 22, 1996*. On July 22, 1996, EPA published a supplemental document in the **Federal Register** (61 FR 37891) on one aspect of its November 23, 1994, **Federal Register** documents; i.e., how the concept of inert ingredient related to plant-incorporated protectants. In 1994, EPA stated that an inert ingredient for plant-incorporated protectants would be ''any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient.'' However, additional information caused EPA to request further public comment on its treatment of inert ingredients, including whether there should be inert ingredients for plant-incorporated protectants.

2. *May 16, 1997*. In August of 1996, Congress enacted the FQPA which amended the FFDCA and FIFRA. On May 16, 1997, EPA published in the **Federal Register** two supplemental documents (62 FR 27132, 27142) to provide the public with an opportunity to comment on EPA's analysis of how certain FQPA amendments to FFDCA and FIFRA affect the proposed tolerance exemptions, and thus, to the proposed exemption of certain plant-incorporated protectants from FIFRA requirements. These supplemental documents are discussed in detail in companion documents published elsewhere in this issue of the **Federal Register** addressing tolerance exemptions for pesticide chemical residues derived through conventional breeding from sexually compatible plants and residues of nucleic acids that are part of a plant-incorporated protectant.

3. *April 23, 1999*. In response to the request that EPA consider another name for this type of pesticide, the Agency published in the April 23, 1999 **Federal Register** (64 FR 19958) a document requesting comment on the advisability of substituting an alternative name for the term ''plant-pesticide,'' and requesting appropriate alternative names for this class of pesticides. EPA also specifically requested comment on whether the alternative name, ''plant-expressed protectants,'' would be an acceptable name for this category of pesticides. EPA noted that if the Agency changed the name of the pesticides termed, ''plant-pesticides,'' the change would only affect the name. It would not affect the status of the pesticidal substance or the genetic material necessary to produce it. The Agency also noted that even with a different name, these would still be pesticides under FIFRA section 2(u), and a change of name would not affect any regulatory requirements.

V. What are the Key Features of this Final Rule?

In this final rule, EPA, first, clarifies that plants used as biological control agents remain exempt from FIFRA requirements, as well as clarifying the relationship between plants and plant-incorporated protectants; second, issues an exemption for a category of plant-incorporated protectants; and third, establishes a new 40 CFR part 174, specifically for plant-incorporated protectants. This rule also imposes a requirement at 40 CFR 174.71 that any person producing, for sale and distribution an otherwise exempt plant-incorporated protectant, who obtains any information regarding adverse effects of this otherwise exempt plant-incorporated protectant on human health or the environment, report that information to EPA. Finally, the rule includes a provision that any claim of confidentiality must be made at the time of submission and substantiated at the time the claim is made.

A. Clarification of Exemption at 40 CFR 152.20; Status of Plants Used as Biological Control Agents with Regard to FIFRA Requirements

This final rule amends 40 CFR 152.20 to clarify that plants used as biological control agents remain exempt from FIFRA regulation, but plant-incorporated protectants will be subject to the requirements of FIFRA unless otherwise exempted. The final rule also refers the reader to 40 CFR part 174 for regulations, including a list of exemptions, on plant-incorporated protectants.

B. Exemption of Plant-Incorporated Protectants Derived Through Conventional Breeding from Sexually Compatible Plants

This rule exempts from all FIFRA requirements, except for the adverse effects reporting requirements at 40 CFR

174.71, plant-incorporated protectants that are derived through conventional breeding from sexually compatible plants. The exempt plant-incorporated protectants represent a subcategory of the plant-incorporated protectants described in Option 1 in the November 23, 1994, **Federal Register** document (59 FR 60522). (EPA is seeking additional comment in a supplemental document published elsewhere in this issue of the **Federal Register** on whether all plant-incorporated protectants derived from plants sexually compatible with the recipient plant should be exempt from FIFRA requirements, regardless of how they are introduced into the recipient plant.)

The following language appears in 40 CFR 174.25 to describe this subcategory:

A plant-incorporated protectant is exempt if all of the following conditions are met:

(a) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient plant.

The following language addressing inert ingredients in plants derived through conventional breeding from sexually compatible plants is added to 40 CFR 174.485, subpart X:

An inert ingredient, and residues of the inert ingredient, are exempt if all of the following conditions are met:

(a) The genetic material that encodes the inert ingredient or leads to the production of the inert ingredient is derived from a plant sexually compatible with the recipient food plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.

(c) The resides of the inert ingredient are not present in food from the plant at levels that are injurious or deleterious to human health.

1. *Associated definitions*. Pertinent definitions associated with the exemption include:

''Bridging crosses between plants'' means the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.

''Cell fusion'' means the fusion *in vitro* of two or more cells or protoplasts.

''Conventional breeding of plants'' means the creation of progeny through either: The union of gametes, i.e., syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses; or vegetative reproduction. It does not include use of any one of the following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion.

''Genome'' means the sum of the heritable genetic material in the plant, including genetic material in the nucleus and organelles.

''Recombinant DNA'' means the genetic material has been manipulated *in vitro* through the use of restriction endonucleases and/or other enzymes that aid in modifying genetic material, and subsequently introduced into the genome of the plant.

''Sexually compatible,'' when referring to plants, means a viable zygote is formed only through the union of two gametes through conventional breeding.

''Source'' means the donor of the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance,

''Vegetative reproduction'' means: In seed plants, reproduction by apomixis; and in other plants, reproduction by vegetative spores, fragmentation, or division of the somatic body.

''Wide crosses'' means to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre-pollination and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures.

Pertinent associated definitions in 40 CFR 174.3, several of which are discussed in Unit VII.B.8., include:

''Active ingredient'' means 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 the production of such a pesticidal substance.

''Genetic material necessary for the production'' means both: Genetic material that encodes a substance or leads to the production of a substance, and regulatory regions. It does not include noncoding, nonexpressed nucleotide sequences.

''Inert ingredient'' means 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 the genetic material is intentionally introduced into a living plant in addition to the active ingredient.

''Living plant'' means a plant, plant organ, or plant part that is alive, viable or dormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems, flowers and pollen.

''Noncoding, nonexpressed nucleotide sequences'' means the sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include, but are not limited to, linkers, adaptors, homopolymers, and sequences of restriction recognition sites.

''Pesticidal substance'' means a substance that is intended to be produced and used in a living plant, or in the produce thereof, for a pesticidal purpose during any part of a plant's life cycle (e.g., in the embryo, seed, seedling, mature plant).

''Plant-incorporated protectant'' means 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 the production of such a pesticidal substance. It also contains any inert ingredient contained in the plant, or produce thereof.

''Produce thereof,'' when used with respect to plants containing plant-incorporated protectants only, means a product of a living plant containing a plant-incorporated protectant, where the pesticidal substance is intended to serve a pesticidal purpose after the product has been separated from the living plant. Examples of such products include, but are not limited to, agricultural produce, grains and lumber. Products such as raw agricultural commodities bearing pesticide chemical residues are not ''produce thereof'' when the residues are not intended to serve a pesticidal purpose in the produce.

''Recipient plant'' means the living plant in which the plant-incorporated protectant is intended to be produced and used.

Other definitions, relevant for plant-incorporated protectants only, can be found at 40 CFR 174.3. In this final rule, ''plant'' means an organism classified using the 5-kingdom classification system of Whittaker (Ref. 1) in the kingdom, Plantae. Therefore, the term ''plant'' includes, but is not limited to, bryophytes such as mosses, pteridophytes such as ferns,

gymnosperms such as conifers, and angiosperms such as most major crop plants.

2. *Reporting of adverse effects for exempted plant-incorporated protectants.* This document publishes a requirement under FIFRA section 3(a) that any person who produces, for sale or distribution an otherwise exempt plant-incorporated protectant, who obtains any information regarding adverse effects on human health or the environment alleged to have been caused by the plant-incorporated protectant, must submit such information to EPA. EPA must receive the report within 30 calendar days of receipt of such information. The language of the requirement is set forth at 40 CFR 174.71, subpart D.

C. Establishment of 40 CFR Part 174

This final rule establishes a new 40 CFR part 174, specifically for plant-incorporated protectants. Subpart A sets forth definitions specific for plant-incorporated protectants, including definitions that are generally applicable throughout part 174. Subpart A also contains procedures for confidential business information. Exemptions from FIFRA are contained in subpart B. Subpart D sets forth the unreasonable adverse effects reporting requirement at § 174.71. A subpart W is established for tolerances and exemptions from the requirement of a tolerance published for residues of plant-incorporated protectants under FFDCA section 408. Subpart X lists the inert ingredients that may be used with plant-incorporated protectants that are exempt from FIFRA and FFDCA requirements.

D. Upfront Substantiation of Confidential Business Information

Procedures for confidential business information are set forth at 40 CFR part 174, subpart A. The rule requires that any claim of confidentiality must accompany the information at the time the information is submitted to EPA, and must be substantiated at the time the claim is made.

VI. How Do the Proposed Rule and Final Rule Differ?

This final rule is adopted with several changes from the 1994**Federal Register** proposed rule. As discussed in the supplemental document published in the April 23, 1999 **Federal Register** (64 FR 19958), EPA has changed the name of this type of pesticide from ''plant-pesticide'' to ''plant-incorporated protectant'' for reasons described at Unit VII.B.2. A second significant change is due to the 1996 FQPA amendment to FIFRA. Because of this amendment, and as discussed in supplemental documents published in the May 16, 1997, **Federal Register** (62 FR 27133, 27143, 27150), ''a pesticide used in or on food that does not meet the FFDCA section 408 safety standard also would pose an unreasonable adverse effect under FIFRA and would not qualify for an exemption from the requirements of FIFRA under FIFRA section 25(b)(2).'' EPA revises the language at 40 CFR 174.21 to add the general qualification that a plant-incorporated protectant used in a food plant can be exempt from FIFRA requirements only if residues of the plant-incorporated protectant in or on food or feed qualify for an exemption from the requirement of a tolerance under FFDCA section 408. (See Unit II. and Unit VII.D.1.iv. for additional discussion). EPA has also determined it will adopt the definition of inert ingredient it proposed for plant-incorporated protectants in 1994 and includes language at 40 CFR 174.21, subpart X, to implement this decision.

EPA in this rule finalizes only a portion of the exemptions it proposed in 1994; specifically, the Agency exempts plant-incorporated protectants derived through conventional breeding from plants sexually compatible with the recipient plant. EPA has received comments that raised significant questions on its 1994 proposed rule, and the Agency is currently considering how to address these questions. In a supplemental document published elsewhere in this issue of the **Federal Register** EPA solicits additional public comment on the various options it is considering to respond to the comments it has already received.

EPA has also narrowed the adverse effects reporting requirement at 40 CFR 174.71 so that only persons who produce plant-incorporated protectants for sale and distribution are responsible for submitting information to EPA concerning adverse effects on human health or the environment caused by the otherwise exempt plant-incorporated protectant. EPA narrowed this requirement in response to comments suggesting that the proposed language could lead to the submission of information that was not relevant to EPA's primary concern of adverse effects caused by the plant-incorporated protectant.

Some modifications, primarily for clarity, or clarification, have also been made to the language of the exemption and associated definitions. These modifications are discussed in this document. Discussion of these modifications can also be found in the documents (Ref. 2) summarizing public comments and EPA response on issues associated with plant-incorporated protectants which can be found in the record for this rule as described in Unit VIII.

VII. Discussion of Final Rule and Public Comments

In this unit, EPA discusses the final rule and summarizes comments it received on the November 23, 1994, **Federal Register** documents. EPA reviewed and considered all comments received on the documents published in the November 23, 1994, **Federal Register** and prepared detailed responses to these comments. These can be found at appropriate points in this preamble, and in the Agency's summary of public comments and EPA's response on issues associated with plant-incorporated protectants (Ref. 2), which is located in the official record for the rule as described in Unit VIII.

A. From Whom Did EPA Receive Comment?

In response to the package of documents published in the **Federal Register** in 1994, EPA received letters from industry, academia, professional and trade associations, government agencies, state regulatory authorities, public interest groups, and private citizens. Some of the commenters sent separate letters for each of the five dockets associated with the 1994 **Federal Register** documents. Other commenters sent a single letter addressed to all five dockets.

On July 22, 1996, EPA published in the **Federal Register** (61 FR 37891) a supplemental document seeking additional comment on how it should view the concept of inert ingredient with regard to plant-incorporated protectants. EPA received comments in response to that supplemental document. On May 16, 1997, EPA published in the **Federal Register** (62 FR 27132, 27142, 27149) supplemental documents to provide the public an opportunity to comment on EPA's analysis of how certain amendments to FFDCA and FIFRA by the FQPA apply to EPA's proposed exemptions under FIFRA for plant-incorporated protectants derived from closely related plants, and proposed exemptions under FFDCA for residues of these plant-incorporated protectants and received comment. On April 23, 1999, EPA published in the **Federal Register** (61 FR 19958) a supplemental document on whether to rename this type of pesticide. EPA received comments on that supplemental document. Copies of all comments received are available in the official record for the rule as described in Unit VIII.

EPA also received comments after the comment period for the rule had closed. Eleven scientific societies sent a report entitled ''Appropriate oversight of plants with inherited traits for resistance to pests'' (Ref. 3). The National Academy of Sciences produced a report entitled ''Genetically modified pest-protected plants: Science and regulation'' (Ref. 4). These comments did not raise issues beyond those that had been raised by comments submitted during the comment period for the rule. Therefore, EPA has not included these comments as part of this rulemaking, and will not respond to them in this action.

B. What Are the Major Comments on EPA's Approach?

More comments supported EPA's approach than opposed it. Comments on EPA's approach to plant-incorporated protectants can be categorized as follows. In general, those comments supporting EPA's approach agree that FIFRA gives EPA the authority to regulate substances that plants produce for protection against pests if humans intend to use these substances for preventing, destroying, repelling or mitigating any pest. Second, the commenters believe an approach that regulates the substance while exempting the plant from regulation is appropriate. Some comments, while in general supporting the approach, had reservations about the definition of plant-incorporated protectant, and definitions directly associated with the definition of plant-incorporated protectant. Others, while recognizing EPA's authority under FIFRA, thought an approach to regulation based on whether genetic engineering, e.g., recombinant DNA (rDNA), was used to introduce genetic material for pesticidal purposes into plants, better addressed risk and public concerns. These commenters urged EPA to implement such an approach.

Those comments opposing EPA's approach can in general be described as: First, those opposed to designating plant defense substances as pesticides, including those that believe that FIFRA should only apply to chemical pesticides; second, those who urged a more narrow definition of plant-incorporated protectant; third, those who believe that use of non-governmental peer review and standards of practice accepted in the plant breeding industry are adequate and EPA oversight is unnecessary; and fourth, those who believe that EPA's approach discriminates against rDNA technology and that any discrimination against rDNA technology is unscientific. There also appears to be some confusion evidenced in comments concerning the concept of ''intent'' in the FIFRA section 2 definition of pesticide. Some comments expressed concern that the term, ''pesticide,'' has a negative connotation with the public. Some of these commenters requested that, at a minimum, plant defense substances not be given the name ''plant-pesticide.''

1. *How can plant defense substances be pesticides?* EPA received seven comments that expressed concern with the designation of defense substances produced by plants as pesticides. Most of these comments stated that it was inappropriate to consider plant defense substances to be pesticides and questioned the Agency's determination that plant defense substances are pesticides.

FIFRA section 2(u) defines ''pesticide'' to include any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. Plant defense substances are clearly pesticides under the FIFRA section 2 definition of pesticide when humans intend to use them ''for preventing, destroying, repelling, or mitigating any pest'' regardless of how the pesticidal capabilities were introduced into the plant (e.g., whether by traditional breeding or through the techniques of modern biotechnology). The suggestion that substances, or mixtures of substances, in plants that humans intentionally use for preventing, destroying, repelling, or mitigating a pest, should not be considered pesticides is not tenable. If the substances were isolated from the plant and sold as pesticides, no one would argue that they were pesticides. Clearly, substances in plants that humans intend to use for preventing, destroying, repelling or mitigating a pest meet the FIFRA section 2 definition of pesticide and Congress has specifically made EPA responsible for regulating pesticides under FIFRA and FFDCA section 408.

2. *Why is EPA giving these pesticides a different name?* EPA recognizes the unique use pattern of these pesticides, which are produced and used in the living plant. Thus, in the November 23, 1994, **Federal Register** (59 FR 60496), EPA suggested giving these types of pesticides a unique name, ''plant-pesticides,'' in order to distinguish them from chemical, microbial, or biochemical pesticides. EPA believes a unique name for this type of pesticides benefits the public by providing the means to more readily identify regulations specific to this type of pesticide in the CFR.

In response to the request that EPA consider another name, the Agency published in the April 23, 1999, issue of the **Federal Register** (64 FR 19958) a document requesting comment on the advisability of substituting an alternative name for the term ''plant-pesticide,'' and requesting appropriate alternative names for this type of pesticide. EPA also specifically requested comment on whether the alternative name, ''plant-expressed protectants,'' would be an acceptable name for this type of pesticide. EPA noted that if the Agency changed the name of such pesticides, the change would only affect the name. It would not affect the status of the pesticidal substance or the genetic material necessary to produce it. Even with a different name, these would still be pesticides under FIFRA section 2(u). Similarly, a change of name would not affect any regulatory requirements.

In response to the April 23, 1999, **Federal Register** supplemental document, EPA received 60 comments. Of these 60 comments, eight comments supported the name ''plant-expressed protectants.'' These commenters argued that the term ''plant-pesticide'' is inappropriate and inaccurate because in standard English it means ''pest killer,'' and many of the pest-resistance mechanisms enhanced by genetic modification do not kill pests in any way, but rather make the crop plants undesirable to pests or not vulnerable to pest attack. These commenters also argued that if plants are labeled as pesticides, a negative connotation could attach to plants. Such plants might be poorly received by the public, and the public perception of a promising branch of science could be tarnished. These commenters also expressed concern that such negative perceptions might lead to labeling requirements or nontariff trade barriers.

Seven comments offered other alternative names without comment on the merit of changing the name. Examples of such names include: Endocides, endogenous bio-control (ebc, or endobio, or endob), enhanced plant protectant, plant protection agent, plant defense agent, plantocides, plendocides, pliocides, intrinsic plant biocontrol agent, intrinsic floral protectant, expressogen, floral defense agent (fda), floral protectant, and gene-transferred protectants.

Eight comments opposed a change of name. These comments, for the most part, thought the name ''plant-pesticide'' appropriate. Some of these commenters argued that the term ''plant-pesticide'' succinctly explains the meaning of the term, i.e., pesticidal

substances introduced into plants. Others arguing for retention of the name ''plant-pesticide'' stated that the term ''pesticide'' does not necessarily have a negative connotation. Several of these commenters asked why the Agency would propose to fix something that is not broken. Several commenters arguing against a change of name stated that EPA should be transparent in its actions, and a pesticide should be called a pesticide. One commenter argued that the term ''plant-pesticide'' has been used by EPA since the early 1990s. It has become a term of art and it would be confusing to change the name. Other commenters stated that if EPA changes the name ''plant-pesticide'' to a more euphemistic name to satisfy one interest group, other interest groups will soon be urging it to change the names of other types of pesticide products to have better marketing potential. These commenters argued against setting such a precedent. Others feared that it would make EPA's effort to control unregistered pesticides more difficult.

Four comments offered alternative names such as Franken-plants, Frankenstein pesticides, Pandora pesticides, products-of-sexual-abuse, alien pesticides, or foreign pesticides.

Among the commenters opposed to a renaming, some also specifically opposed the term ''plant-expressed protectants''. Those opposed to the name ''plant-expressed protectants'' stated that the name obscures the legal issues and attempts to mislead the public into believing that these pesticides are not pesticides at all.

After reviewing all comments, EPA decided to change the name of this category of pesticides from ''plant-pesticides'' to ''plant-incorporated protectants.'' From comments EPA has received both in the comment period on the 1999 supplemental document discussing the possibility of changing the name, and over the years since the 1994 proposed rule was issued, the Agency concludes that many people are not aware of, or do not understand, the FIFRA definition of pesticide. For example, some comments argued that the term ''plant-pesticide'' is inappropriate and inaccurate because it means ''pest killer'' and many pest-resistance mechanisms do not kill pests but rather make the plant undesirable or not vulnerable to pest attack. EPA notes that the term ''pesticide'' in FIFRA section 2 means, in part, ''any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.'' A pest-resistance mechanism that makes the plant undesirable or not vulnerable to pest attack falls within the definition of pesticide because such mechanisms ''prevent'' or ''repel'' a pest. EPA recognizes that the term ''protectant'' may better describe for the general public pesticides in plants that function by preventing, repelling or mitigating a pest because the term encompasses these concepts, in addition to the concept of destroying a pest. A number of suggested names received in response to the April 23, 1999, **Federal Register**, document utilized the word ''protectant.''

In addition, the name ''plant-pesticide'' appears in some instances to have led some people to believe the Agency is regulating plants, despite the Agency's numerous statements that EPA would not regulate the plant per se, but rather substances within the plant when these were used for pesticidal purposes. EPA recognizes that the name ''plant-pesticide'' may have contributed to this confusion, as some people may interpret the term ''plant-pesticide'' to mean a ''plant that acts like a pesticide.'' EPA believes the adjective ''plant-incorporated'' more accurately conveys the sense that these pesticides are produced and used in the plant. EPA will therefore utilize this adjective in concert with the term ''protectant'' to describe this type of pesticide. EPA chose the adjective ''plant-incorporated'' rather than the adjective ''plant-expressed,'' because the word ''expressed'' represents a technical term of art, and in this instance it appeared preferable to use the term ''incorporated'' which also encompasses a meaning found in the common English dictionary (Ref . 5), i.e., ''joined or combined into a single unit or whole''. The term ''plant-incorporated'' may thus be better understood by the general public than the term ''plant-expressed.''

EPA discounted names received in comments that focus inaccurately on pesticides introduced into plants through genetic modification, e.g., gene-transferred protectants. Names focusing on those pesticides introduced into the plant through the techniques of genetic engineering are too limited, in that such names do not describe the full range of this type of pesticide. This rule addresses pesticides that can be present in a plant because they evolved in the plant, were moved between plants through mating, or were introduced into plants through the techniques of modern biotechnology (e.g., rDNA).

With regard to the concern that other interest groups will soon urge the Agency to change the names of other types of pesticide products to have better marketing potential, EPA recognizes that this may indeed be the case. Indeed, one commenter on the April 23, 1999 **Federal Register** document supplied lengthy comments supporting a name change, and indicating that in the future his organization will suggest that EPA initiate a rulemaking to adopt other terms to describe other products which are regulated under FIFRA. EPA will evaluate each such request on its own merits.

It is not clear to EPA how changing the name of this type of pesticide would affect the Agency's ability to control unregistered pesticides. The comment did not provide a description of how this might occur. As previously stated, the name of the product does not affect the manner in which it is sold or intended to be used, which determines whether a product falls within EPA's jurisdiction under FIFRA.

3. *Does FIFRA apply to pesticides other than traditional pesticides?* EPA does not agree with the contention that FIFRA was meant to regulate only chemical pesticides, such as those extracted from plants or synthesized by petroleum chemistry. The definition of pesticide in FIFRA section 2(u) is not, and has never been, limited to chemical pesticides. Indeed, FIFRA section 2(u) specifically states that a pesticide is any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant or desiccant or a nitrogen stabilizer. Pesticides other than chemical pesticides have been, and continue to be, registered under FIFRA. The first microbial pesticide was registered in 1948 and other biological substances, e.g., pheromones, have been regulated by EPA as pesticides since 1979. Moreover, in 1975, the Committee on Agriculture of the House of Representatives during the debate on the bill (House Report 8841) to extend FIFRA, as amended, for one year, specifically rejected a proposed amendment that would have excluded from the definition of pesticide ''biological parasites, living organisms and predators of pests'' other than microorganisms such as bacteria, fungi or viruses (Ref. 6). Congress again acknowledged in 1996 that the term ''pesticide'' is not limited to chemicals when it enacted FIFRA section 3(c)(10)(B) and established expedited review for both ''biological and conventional pesticides'' (7 U.S.C. 136a(c)(10)(B)). Plant-incorporated protectants, microbial pesticides, biochemicals and semiochemicals (e.g., pheromones) are included under the rubric of biological pesticides.

EPA also does not agree with the implication that risks associated with

pesticide use stem only from the use of chemical pesticides. While EPA believes that as a pesticide class, biological pesticides are more likely to present lower levels of risk, there are certainly chemical pesticides that also fall into the category of ''safer pesticides.'' There may also be biological pesticides, including some plant-incorporated protectants, that could present higher levels of risk.

4. *Why has EPA not implemented a narrower definition of plant-incorporated protectant?* Some comments urged EPA to adopt a more narrow definition of plant-incorporated protectant. These comments include those who urged EPA to define plant-incorporated protectants to be only those pesticidal substances that are introduced into plants from sources outside the plant kingdom, and those who urged the Agency to utilize toxicity to define a plant-incorporated protectant.

FIFRA section 2 defines pesticide broadly as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant or a nitrogen stabilizer (7 U.S.C. 136 (u)). The FIFRA section 2 definition of pesticide does not make any reference to conditions such as origin nor the level or kind of toxicity that a product must exhibit in order to be considered a pesticide. Instead of defining a substance either in or out of FIFRA based on its toxicity or origin, FIFRA section 25(b) authorizes EPA to exempt pesticides from FIFRA requirements. In the actions it takes today, EPA exempts plant-incorporated protectants derived through conventional breeding from sexually compatible plants. These actions significantly reduce the number of plant-incorporated protectants subject to FIFRA requirements, although they have no effect on the FIFRA section 2 definition of pesticide.

5. *How do substances produced and used in living plants meet the intent standard in the FIFRA definition of pesticide?* EPA received comments indicating some confusion may exist in the broader community regarding the concept of ''intent'' in the FIFRA section 2(u) definition of pesticide, and in how this concept applies to plant-incorporated protectants. One comment, for example, argued that plant defense substances should not be pesticides and stated that by ''strict interpretation of the FIFRA definition of pesticide, substances produced by plants that provide protection against pests and disease cannot be considered pesticides because plants do not 'intend' nor 'produce to protect themselves.''' The commenter went on to state that ''this argument would certainly be correct for wild plants because only natural selection has been involved in stabilization of the character. This argument would also hold for many cases of cultivars improved through breeding programs because many times breeders select for the best yielding plants without specific regard to specific disease or pest; thus there is no intent.''

A key statutory element in the FIFRA definition of pesticide is whether a human ''intends'' that a substance or mixture of substances be used for destroying, preventing, repelling, or mitigating a pest. Just as EPA does not evaluate whether a granule of a traditional chemical pesticide ''intends'' to function as a pesticide in determining whether a substance is a pesticide, the Agency did not base its determination that plant-incorporated protectants are pesticides on the belief that a plant ''intends'' to prevent, destroy, repel, or mitigate a pest. Rather, EPA considers the actions of the humans selling, distributing, or using the substance. To the extent a human relies on a plant's existing pest control properties, the human demonstrates pesticidal intent; if he or she uses, or sells a plant knowing that it typically produces a pesticidal substance he or she ''intends'' for it to be produced. For example, EPA considers that a clear human intent is present when a seller or distributor claims, states, or implies (by labeling or advertising or otherwise) that a substance or organism, either by itself or in combination with other substances or organisms, can or should be used as a pesticide. An example of this would be a company advertising that the cotton seed it is selling would produce cotton plants expressing an insecticidal protein effective against lepidopteran pests. Another example of intent would be a company advertising that a certain variety of squash resists fungal disease.

Yet a third example of a situation where a human displays a pesticidal intent involves a person who sells or distributes a product with actual or constructive knowledge that the product will be used, or is intended to be used, for a pesticidal purpose (see 40 CFR 152.15). EPA considers that the person introducing genetic material encoding a pesticidal substance into a plant displays such an intent. For example, the Bt delta-endotoxin is a well-known insecticidal protein with no other known function; introduction of such a protein into a plant displays a clear pesticidal intent.

Another example of such intent is the use of a name for the product which includes the name of a substance commonly recognized as having pesticidal properties. Such a product will be recognized as a pesticide because the targeted consumer would recognize from the product name that the product contains a pesticide.

A substance in a plant evolving in the wild in response to natural selection is not subject to FIFRA until a human intends the substance to be sold, distributed in commerce, or used to prevent, destroy, repel, or mitigate a pest. Similarly, a cultivar selected, sold and distributed with reference only to yield considerations, without exhibiting any indicia of intent for the cultivar to be used as a pesticide, does not contain substance(s) meeting the FIFRA section 2(u) definition of pesticide. EPA would not treat such a cultivar, or a substance within it, as a pesticide until a human exhibits the requisite intent that the substance(s) or cultivar be used for preventing, destroying, repelling or mitigating a pest.

6. *Why does EPA have a role to play, in light of peer review and existing standards of practice in the plant breeding industry?* Some commenters opposed to EPA's approach argued that use of non-governmental peer review and standards of practice accepted in plant breeding are adequate. As discussed in Unit VII.A.5., whether a substance is a pesticide under the FIFRA section 2 definition depends on the intent of those selling or distributing it. Once something falls within the FIFRA definition of a pesticide, it must generally be registered before it can be sold or distributed in the United States, unless EPA can make the requisite findings to exempt it. For some plant-incorporated protectants, EPA believes that there are circumstances where it is necessary that the Agency employ its statutory authorities to ensure use will not cause unreasonable adverse effects on the environment, and/or ensure that residues of the plant-incorporated protectant can be safely consumed. Some plant-incorporated protectants may be isolated from novel sources (e.g., scorpions, frogs, microorganisms), and may present novel, unknown and/or unfamiliar, toxicological profiles. For example, most of the plant-incorporated protectants reviewed to date by EPA have been insecticidal proteins isolated from microbial sources. These insecticidal proteins are regulated by EPA when they are formulated to be sprayed/dusted on plants. Many of the risk considerations associated with use of the insecticidal proteins in the sprayed/dusted product are present

when the proteins are formulated as a plant-incorporated protectant, even though the route of exposure may be different for the different formulations.

There are also substances that occur naturally in plants, including major crop plants, that can cause toxic effects when present at high concentrations or when presented in novel exposures (Refs. 7 and 8). As these substances could be used as plant-incorporated protectants, EPA believes it is important for the Agency to be able to employ its statutory authorities to ensure use will not cause unreasonable adverse effects on the environment.

EPA, nonetheless, recognizes that plant breeding in the United States has a good record of providing a safe food supply and that plant breeders employ accepted standards of practice to maintain this record. This good record provides support to the Agency's determination that it can exempt plant-incorporated protectants derived through conventional breeding from sexually compatible plants from almost all regulatory oversight, relying only on the post-market reporting of adverse effects. EPA believes that the clarification in this rule that the Agency will not regulate plants per se, in conjunction with the exemption it is issuing today, limits EPA's regulatory role in conventional plant breeding and ensures that the Agency does not unnecessarily supplant the self-regulating aspects of plant breeding.

Some comments that in general otherwise supported EPA's approach, encouraged EPA to ensure that pest resistant crops derived by conventional plant breeding are not subjected to unnecessary regulation. As explained above, EPA believes that its clarification that it would not regulate plants per se, and the exemption it is issuing today, limit EPA's regulatory role in conventional plant breeding and ensures that the Agency does not subject pest-resistant crops derived by conventional breeding to unnecessary regulation.

7. *What were the comments on regulatory procedures?* One comment recommended that, before EPA's regulations are finalized, EPA address issues such as labeling, and field testing and seed production. Another comment recommended that the Agency develop guidelines, in conjunction with the scientific community and industry, to help those who are developing products from these new technologies to determine the factors and situations that might merit regulation by the EPA.

Subsequent to publication of the 1994 **Federal Register** documents, EPA under existing regulations in 40 CFR parts 152 through 173 and 40 CFR parts 177 through 180, took several actions with regard to plant-incorporated protectants. EPA issued, for example, a number of EUPs for field testing of plant-incorporated protectants, exemptions from the requirement of a tolerance for residues of plant-incorporated protectants, and registrations for plant-incorporated protectants.

Together, these actions show how EPA to date has approached labeling, field testing, large scale planting for seed increase, and data needs for evaluating plant-incorporated protectants. In the future, EPA anticipates proposing additional regulations for plant-incorporated protectants that would tailor existing regulations for pesticides so that the procedures would better fit the characteristics of plant-incorporated protectants. Until such regulations can be issued, EPA will continue to apply the regulations in 40 CFR parts 152 through 173 and 40 CFR parts 177 through 180 to plant-incorporated protectants, unless superceded by the regulations published in 40 CFR part 174.

i. *How has EPA approached labeling?* One commenter asked whether labels are expected to appear on bags of seed, and, if so, what information should be on the label. Labeling is generally required by FIFRA for pesticides. Labeling includes both written material accompanying the pesticides and labels on or attached to the pesticide, its container, or wrapper (7 U.S.C. 136 (p)). In its 1994 policy statement for plant-incorporated protectants, EPA attempted to provide the broad outlines of how it would approach labeling. The Agency recognized in the 1994 **Federal Register** policy statement (59 FR 60510) that certain types of labeling which are appropriate for chemical pesticides will not be practical for plant-incorporated protectants. In issuing registrations for plant-incorporated protectants, EPA has followed the labeling regulations at 40 CFR part 156. Under current procedures for plant-incorporated protectants, the pesticide label is held by the producer or the producer's agent(s) and is attached to seed sent to seed propagators. The actual pesticide label requires that informational material must be provided to the farmer with bags of seed sold to farmers. The informational material should indicate that the seed contains a registered plant-incorporated protectant, and its primary purpose is to prevent needless spraying of chemical pesticides. The informational material also conveys any other information pertinent to the grower on the registration and use of the plant-incorporated protectant. Recognizing that the regulations at 40 CFR part 156 were written for chemical pesticides, EPA intends in the future to propose at 40 CFR part 174, labeling requirements specifically tailored for plant-incorporated protectants. No label of any type is required for the plant-incorporated protectants exempted in new 40 CFR part 174.

ii. *How has EPA approached seed increase?* One commenter noted that to produce seed for sale, companies will need to plant significant acreage to generate commercial quantities of seed. The commenter asked how such developmental work will be carried out, as such work does not fall under the traditional usage of an Experimental Use Permit (EUP), because an EUP is granted for generation of data to support registration. Since 1994, EPA issued three ''seed increase'' registrations. Seed increase registrations were issued to allow producers to grow seed for commercial sale, and were limited to seed increase activities. Most registrants, however, currently obtain a registration prior to beginning seed increase activities sufficiently large to produce seed for commercial sale and distribution.

iii. *What is EPA doing in terms of guidance?* With regard to the comment that the Agency develop guidelines to help those who are developing products from these new technologies, EPA, in its November 23, 1994 **Federal Register** policy statement (59 FR 60511), attempted to provide a general perspective on information needs for plant-incorporated protectants. The Agency in the future intends to establish data requirements specific to plant-incorporated protectants through a public notice and comment process. In establishing these testing requirements, EPA will propose the tests it believes are appropriate, indicating the circumstances when each study would be required, conditionally required, or not required. These proposed requirements will be widely available for public comment and will be reviewed in a public meeting of the FIFRA SAP. Amendments can be made to the proposed guidelines as part of the notice and comment process. EPA has already begun this process with the public meetings on December 8, 1999, February 29, 2000 and June 7, 2000 of the FIFRA SAP on data requirements for product identity, human health and non-target organism effects of proteineous plant-incorporated protectants.

8. *What comments were received on the definitions?* Some commenters who supported EPA's approach thought the

plant-incorporated protectant definitions and other associated definitions appropriate. Other comments, while in general supporting the approach, expressed reservations about the definitions. These comments focused primarily on three issues: First, whether the ''genetic material necessary for the production'' should be part of the plant-incorporated protectant definitions; second, clarification of how this term is to be interpreted in several specific circumstances, e.g., with regard to multiple copies of a gene; and, third, what the term ''living'' was intended to signify in the definitions, particularly with regard to regulation of plant-incorporated protectants intended for post-harvest pest control.

i. *Why is EPA including genetic material in the plant-incorporated protectant definitions?* EPA received several comments on including ''genetic material necessary for the production'' in the plant-incorporated protectant definitions. Some comments supported inclusion. Other commenters opposed including genetic material in the definitions for various reasons: First, that inclusion of genetic material in the definition runs counter to the traditional definition of pesticide. Second, commenters disagreed with the presumption that the presence in a plant of genetic material necessary for producing a pesticidal substance indicates a pesticidal intent since the genetic material will still be in the plant when there is no longer any ''pesticidal intent,'' e.g., once a crop has been harvested and regenerative material no longer used for future plantings. Third, commenters argued that including the genetic material necessary for the production in the plant-incorporated protectant definitions is not necessary for EPA to be able to request data on the genetic material. Fourth, commenters asserted that including genetic material in the definitions results in EPA effectively regulating the whole plant because genetic material is found in all parts of the plant. Fifth, commenters alleged that inclusion of the genetic material in the definitions makes EPA's approach inconsistent with policies of the Food and Drug Administration (FDA). Sixth, the comments raised arguments that inclusion of genetic material in the definitions would add an unnecessary layer of complexity to the regulatory process. One commenter suggested that EPA should, on the basis of the above listed considerations, reevaluate EPA's inclusion of the genetic material in the plant-incorporated protectant definitions. The comment suggested that if the Agency concludes that ''genetic material'' must remain in the plant-incorporated protectant definitions, it should be an inert ingredient, not part of the definition of active ingredient.

Based on several considerations, EPA has determined that the ''genetic material necessary for the production'' will continue to be part of the plant-incorporated protectant definitions. First, the conclusion that such genetic material is part of a plant-incorporated protectant is consistent with FIFRA which defines ''pesticide'' broadly, and encompasses both single substances and mixtures of substances intended for preventing, destroying, repelling or mitigating a pest. The genetic material and the substance it encodes for are such a mixture. In this instance, the genetic material is introduced into the plant with the intent to cause a pesticidal effect; i.e., with the intent that the substance(s) produced from this genetic template will ultimately result in a pesticidal effect. Thus, the genetic material, as well as the pesticidal substance, are introduced with the intention of obtaining a pesticidal benefit. Both the genetic material and the pesticidal substance meet the FIFRA statutory definition of pesticide. Second, including the genetic material in the definitions permits EPA to address plant-incorporated protectants during stages of the plant's life cycle or in plant parts (e.g., in pollen or seed) where the pesticidal substance itself is not produced or is produced in amounts below the limits of detection. EPA believes that including the genetic material in the definitions maintains regulatory continuity during such periods in a plant's life cycle and has concluded that this regulatory continuity is important for comprehensively addressing potential risks associated with plant-incorporated protectants within a cohesive and rational regulatory policy. Third, inclusion of the genetic material in the definitions allows the Agency to more readily verify the presence of the plant-incorporated protectant in the plant or plant material because, in many instances, it may be more difficult technically to assay for the substance than it is to assay for the genetic material. Fourth, inclusion of genetic material in the definitions allows EPA to address the spread of the pesticidal substance in the environment through the spread of the genetic material necessary for the production of the pesticidal substance.

a. *Why is inclusion of genetic material in the definition consistent with the traditional use of the term pesticide?* Many of the commenters that disagreed with the inclusion of genetic material in the plant-incorporated protectant definitions argued that including the genetic material runs counter to the traditional use of the term, ''pesticide.''

EPA finds that inclusion of the genetic material in the plant-incorporated protectant definitions is consistent with FIFRA. FIFRA section 2(u) defines the term ''pesticide'' broadly to include ''any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest'' (7 U.S.C. 136 (u)). Section 2(u) defines a pesticide in terms of the intent of humans to exert a deleterious effect upon pests. It does not limit pesticides to substances that directly cause such a deleterious effect (7 U.S.C. 136 (u)). Indeed, EPA has registered chemical substances that do not directly have pesticidal effects but which, when applied to plants, are transformed into the substance having the actual pesticidal effect.

Consistent with FIFRA section 2(u), EPA has concluded that the genetic material necessary for the production of a pesticidal substance, intentionally introduced into a plant, meets the FIFRA statutory definition of a pesticide. Such material is introduced into a plant with the intent of ultimately producing a pesticidal effect even though the genetic material may not itself directly affect pests. The commenter did not identify any specific instances of past Agency usage that would conflict with this conclusion, and EPA is not aware of any.

b. *Why is the genetic material part of the active ingredient definition?* EPA does not agree with the comment suggesting that the genetic material be considered an inert ingredient and not part of the active ingredient. In deciding to include the genetic material necessary for the production of a pesticidal substance in the definition of active ingredient, the Agency considered the statutory definitions of inert and active ingredients. Based on these definitions, EPA concluded that the genetic material necessary for the production of a pesticide fit more closely within the section 2(a) definition of ''active ingredient.'' Section 2(a) defines an active ingredient as, among other things ''the ingredient which will prevent, destroy, repel, or mitigate any pest'' (7 U.S.C. 136(a)(1)). The genetic material is a necessary component of the ability of the plant-incorporated protectant to prevent, destroy, repel or mitigate a pest, as without the genetic material the plant cannot produce the pesticidal substance (See also, 7 U.S.C. section 136(a)(2)). Moreover, the genetic material was inserted with the intention

of obtaining a pesticidal effect: the expression of a substance that will prevent, destroy, repel, mitigate any pest. Consequently, EPA will not define the genetic material necessary for the production of a pesticidal substance as an inert ingredient, as suggested by comment.

c. *How does including genetic material in the definitions relate to EPA's ability to request data?* EPA received comment stating that the Agency has the authority to require all relevant data for a plant-incorporated protectant, including data related to the genetic material, regardless of whether the genetic material is part of the definitions. The same comment noted that deleting the phrase ''genetic material necessary for the production'' from the definitions will not prevent EPA from addressing salient issues related to the spread of genetic material in the environment, or to the levels of the pesticidal substance present in the plant.

EPA agrees that it has broad authority under FIFRA to gather and review data/information on any aspect of a pesticide product or its use in the environment, including data on fate in the environment. However, if a particular aspect of a plant-incorporated protectant is not part of the active or inert ingredient definition for plant-incorporated protectants, it is part of the plant and this rule clarifies that the plant is exempt under FIFRA section 25(b)(1) from FIFRA requirements (40 CFR 152.20). Thus, data gathering considerations are not the primary reason the Agency is including the genetic material in the definitions.

The comment also stated, with regard to EPA's argument that including the genetic material in the definitions permits the Agency to address plant-incorporated protectants during stages of the plant's life cycle where the pesticidal substance itself is not produced, that EPA has the authority to address pesticides at various stages of the product's life cycle, in soil, water and food without including the genetic material in the definitions. EPA agrees that it has the authority to control pesticide residues and the metabolites and degradates of pesticides in the environment and in food. However, as previously noted, unless the genetic material is part of the plant-incorporated protectant, it will be exempt under 40 CFR 152.20. The Agency also believes that in certain circumstances for technical reasons it is easier to identify the presence of the genetic material than the pesticidal substance, and considered this in deciding whether to include the genetic material in the definitions.

d. *Is inclusion of the genetic material in the definitions a disincentive to developers?* The comment provided no specific reason why inclusion of genetic material in the definitions would hinder product development or increase costs. EPA has registered eleven plant-incorporated protectants to date, and including the genetic material in the definitions does not appear to have discouraged companies from developing plant-incorporated protectants.

e. *Is inclusion of the genetic material in the definitions consistent with the assumption of ''intent''?* One commenter opposed EPA's proposal to include the genetic material necessary for production of the pesticidal substance in the definitions of active ingredient and plant-incorporated protectant on the grounds that it is inconsistent with EPA's longstanding implementation of FIFRA, as well as the statute. Specifically, the commenter disagreed with EPA's statement that the genetic material ''is introduced into the plant with the intent that it will ultimately result in a pesticidal effect,'' alleging that this equates the presence of genetic material with pesticidal intent, and fails to acknowledge that a substance can have both pesticidal and non-pesticidal uses, depending on how the substance is intended to be used. The commenter contended that ''once the crop has been harvested and regenerative material removed for future plantings, any genetic material that remains in the food, feed, or other product no longer is accompanied by any 'pesticidal intent.'''

EPA disagrees that its decision to include the genetic material in its definitions of a plant-incorporated protectant and active ingredient fails to adequately recognize the role ''intent'' plays under FIFRA, or that its decision necessarily equates the presence of genetic material with pesticidal intent. The commenter appears to have misunderstood EPA's statements on this issue, and their implications with respect to EPA's regulation of such substances under FIFRA.

As a preliminary matter, EPA believes that including the genetic material necessary to produce a pesticidal substance in the plant-incorporated protectant definitions is consistent with key statutory definitions, as explained at length in Unit VII.B.8.i. FIFRA section 2(u), defines pesticide to include ''any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest'' (7 U.S.C. 136(u)). Under FIFRA, a substance is a pesticide if it is intended to be used for a pesticidal purpose. And as EPA has previously explained, substances that are sold or distributed with the intent that they ''prevent, destroy, repel, or mitigate any pest'' fall within the FIFRA section 2(u) definition of a pesticide. In the absence of other facts indicating a contrary intent, EPA believes that it is reasonable to presume that the introduction into a plant of genetic material that produces, or is intended to produce, a pesticidal substance is clear evidence of a pesticidal purpose. EPA's interpretation is based on the fact that without the genetic material, the pesticidal substance, the substance that will actually ''prevent, destroy, repel, or mitigate any pest,'' cannot be produced by the plant. The sole reason the genetic material is inserted into the plant is to ensure that the pesticidal substance is produced. This is fully consistent with EPA's approach to traditional chemical pesticides (see, 40 CFR 152.15(b)).

However, regulation of the genetic material necessary for the production of a pesticidal substance as an active ingredient or a plant-incorporated protectant in one plant does not mean that some portion of the genetic material cannot be used for another purpose without being subject to FIFRA. At no time has EPA stated that, for example, once a particular promoter is used as part of the construct inserted to produce a pesticidal substance in a plant, thereafter, irrespective of the rest of the genetic construct that is inserted, EPA will always consider insertion of the promoter to demonstrate pesticidal intent. Rather, EPA's statement was intended to clarify that, in the absence of indicia indicating a contrary intent, because the purpose of the introduced genetic material is to produce a pesticidal substance, the insertion of the genetic material will be taken as evidence of a pesticidal intent, and the resulting product will be considered a pesticide under FIFRA. In Unit VII.B.5., EPA discusses in some detail, examples of actions that the Agency interprets as indicia of a pesticidal intent. Clarity on this point is of particular concern with respect to these products because the plant in which the plant-incorporated protectant is contained will remain exempt, and anything that is not part of the plant-incorporated protectant will therefore not be regulated by the Agency under FIFRA.

Thus, EPA agrees with the commenter that under some circumstances the pesticidal intent would cease after harvest, and under such circumstances, the sale of the produce as food or feed would be subject to the FFDCA, rather than FIFRA. The mere presence of such genetic material in the produce will not

cause EPA to treat the produce as a pesticide, absent any indicia of intent to sell, distribute in commerce, or use the produce itself as a pesticide, any more than the presence of traditional pesticide chemical residues renders a food bearing those residues a pesticide. However, if the produce is intended to be used, sold or distributed as containing a plant-incorporated protectant, EPA will regulate it as such. To clarify this, EPA has revised the definition of plant-incorporated protectant, and included a definition of the term ''produce thereof,'' to specifically exclude the products of a plant-incorporated protectant merely bearing ''pesticide chemical residues,'' such as the genetic material, from the definition of a plant incorporated protectant, when the plant-incorporated protectant in the produce is not intended to provide post-harvest control. EPA provides further discussion of its treatment of products that are intended to provide post-harvest control in Unit VII.B.8.iii., and the associated response to comments document (Ref. 2).

The question of pesticidal intent arises in making the determination that the substance being sold or distributed in commerce is a pesticide that must be registered under FIFRA, or whose use is subject to regulation under section 3(a), and for which a tolerance must be granted under section 408 of the FFDCA to permit food or feed bearing the residues of that substance to be introduced into interstate commerce. Unless the Agency is attempting to regulate the produce as a pesticide, the issue of post-harvest control is irrelevant. Thus, as explained in the preceding paragraph, the issue of post-harvest control is essentially irrelevant to EPA's interpretation that the introduction of genetic material into a plant that is expected to ultimately produce a pesticidal effect provides evidence of pesticidal intent, absent any other indicia to the contrary.

In addition, EPA offered in 1994 several reasons in support of its decision to include the genetic material necessary to produce the pesticidal substance, as well as the pesticidal substance, in the definition of a plant-pesticide (59 FR 60521). None of them rested on an assumption that evidence of a pesticidal intent would always be present after harvest.

This approach is fully consistent with the Agency's approach to traditional chemical pesticides. For example, the Agency follows the fate of traditional chemical pesticides in the soil after the harvest of the crop and during rotational crop plantings, even when there is no intent to ''prevent, destroy, repel, or mitigate any pest'' after harvest or during later plantings. This allows EPA, as required by FIFRA, to ensure that a pesticide ''when used in accordance with widespread and commonly recognized practice, . . . will not generally cause unreasonable adverse effects on the environment'' (see 7 U.S.C. sections 136a(c)(5) and 136d). This requirement applies even when the intent of preventing, destroying, repelling or mitigating a pest is no longer evident; for example, as part of its regulation of pesticides EPA considers whether pesticide residues or metabolites can migrate into groundwater, even though there is no intention of obtaining a pesticidal effect from the presence of these substances in groundwater.

f. *How does the genetic material in the definitions relate to the whole plant?* Comments disagreeing with the inclusion of the genetic material in the definitions also argued that including the genetic material ''calls into question EPA's assertion that it has no intention of regulating the plant, since the 'genetic material' will be present in all parts of the plant and in products derived from the plant.''

EPA does not believe that including the genetic material in the definitions calls into question EPA's assertion that it has no intention of regulating the plant. The comment did not explain how regulation of the genetic material would lead to regulation of the whole plant, nor how regulation of genetic material would result in a different outcome in this regard from regulation only of the substance produced from the genetic material. EPA clarifies in this document that plants used as biological control agents are exempt at 40 CFR 152.20. As a result, EPA is not regulating plants or varieties of plants. Rather, the Agency regulates the plant-incorporated protectant (i.e., the pesticidal substance, the genetic material necessary for the production of the pesticidal substance, and any inert ingredient) for use in a particular type of plant (e.g., cotton). To date, EPA has registered several plant-incorporated protectants, and all have been registered for use in the crop, rather than plant variety by plant variety. Moreover, changes to a plant that are unrelated to the plant-incorporated protectant would not be regulated by EPA, but by the United State Department of Agriculture (USDA) and the FDA. For example, changing the color of Bt cotton with the intent of marketing undyed but nonetheless colored cotton would be evaluated by the USDA and FDA (if the cottonseed were to be processed for meal or oil in food or feed uses), even though EPA would evaluate and regulate the effects of the pesticide, Bt.

g. *Is inclusion of the genetic material in the definitions consistent with FDA policy?* One comment suggested that inclusion of the genetic material in the definition of plant-incorporated protectant makes EPA's approach inconsistent with FDA's 1992 Statement of Policy for Foods Derived from New Plant Varieties (57 FR 22984). The comment stated that in its 1992 policy, FDA recognized that genetic material is present in the cells of every living organism and as a result should be presumed to be ''generally recognized as safe.''

EPA disagrees that its approach is inconsistent with the 1992 policy issued by FDA. EPA is publishing elsewhere in this issue of the **Federal Register** an exemption from the FFDCA section 408 requirement of a tolerance, for residues in or on food or feed of nucleic acids that are part of a plant-incorporated protectant. This exemption from FFDCA section 408 requirements applies to the genetic material necessary for the production of a pesticidal substance. Part of the rationale supporting EPA's FFDCA exemption is that nucleic acids are ubiquitous in nature and have always been present in human food and domestic animal feed and have been consumed without harm. This rationale is consistent with FDA's rationale which considers genetic material in food to be ''Generally Recognized as Safe'' (GRAS). EPA believes its approach under FFDCA is consistent with FDA's approach under FFDCA. FIFRA does not automatically exempt substances FDA has classified as GRAS. Instead, FIFRA requires entities who wish to sell or distribute a pesticide to either register the pesticide or seek an exemption from FIFRA requirements prior to such use. For example, garlic used as a pesticide, was registered until EPA exempted it at 40 CFR 152.25(g) as a minimum risk pesticide. Any person may petition EPA to establish an exemption pursuant to FIFRA section 25(b) and FFDCA section 408(d). EPA will make every effort to expedite its review of such petitions.

h. *Does inclusion of the genetic material in the definitions create an overly complex regulatory process?* One comment stated that inclusion of the genetic material in the definitions will result in regulatory uncertainty. The commenter did not explain how inclusion of the genetic material in the definitions would lead to such uncertainty, and EPA assumes that this commenter's uncertainty is related to issues posed by the following questions.

Are all the genes in the vector used to transform the plant covered by the definition? If fragments of a gene are present in the plant, but do not encode a pesticidal substance, are the fragments covered by the definition? Would a producer need to provide EPA with the number of copies of the genes that are introduced into the plant? Would the number of copies be a consideration in the registration process, e.g., in determining when a separate, distinct registration is required? How would changes in regulatory regions affect the status of a registered product; for example, would a new registration be required for a change in a promoter?

EPA does not believe that inclusion of the genetic material in the definitions will lead to an unnecessary layer of complexity in the regulatory process. Because the questions posed by the commenter relate to how EPA views the phrase, genetic material necessary for the production of the pesticidal substance, EPA responds in Unit VII.B.8.ii. to the specific questions posed with regard to the genetic material.

ii. *How is the phrase ''genetic material necessary for the production'' to be interpreted?* EPA's analysis of, and response to, the specific questions posed with regard to the genetic material follows. While conceptually parts of this analysis could apply to exempt as well as non-exempt plant-incorporated protectants, the analysis has practical relevance only for those plant-incorporated protectants that are not exempt from FIFRA requirements and are, or are to be, regulated. For example, the discussion in Unit VII.B.8.ii. on the Confidential Statement of Formula is only relevant to registered plant-incorporated protectants.

a. *How does EPA view genetic material introduced into the plant but not expressed in the plant?* One of the questions posed by comment was whether all the genetic material in a vector used to transform a plant is considered to be part of a plant-incorporated protectant, even if some of the genetic material on the vector is not expressed in the plant and does not play a role in regulation of expression of the pesticidal substance in the plant. A second question concerned the status of gene fragments that do not express a pesticidal substance.

EPA does not intend that all genetic material present in the genetic insert (e.g., in a vector) introduced into the plant must be considered part of the plant-incorporated protectant. EPA defines the term, ''genetic material necessary for the production'' to mean ''genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance and regulatory regions.'' To more fully describe how EPA interprets this language, two scenarios are discussed.

The first scenario involves sequences that do not function as regulatory regions in the plant but do so in other organisms (e.g., in bacteria). For example, quantities of the genetic material intended to be introduced into a plant are often prepared through fermentation of bacteria containing the desired genetic material on pieces of genetic material called plasmids. To prepare the genetic material, large quantities of bacteria are grown and the plasmids they contain are isolated for subsequent introduction into plant cells. One specific segment of genetic material in these plasmids, called an origin of replication, controls the replication of the plasmids in the bacterium. Even though these origins of replication only function as regulatory regions in bacteria, for technical reasons, they are sometimes part of the genetic material introduced into the plant along with the genetic material that encodes for, or leads to the production of a pesticidal substance. These plasmid origins of replication would not be considered part of the plant-incorporated protectant, because they do not encode for a pesticidal substance nor do they lead to production of the pesticidal substance in the plant, i.e., they do not function as regulatory regions in the plant. Genetic material necessary for vector maintenance/transfer in an intermediate host system (e.g., bacteria) and having no function in the plant would not be considered part of a plant-incorporated protectant. Sequences that function as regulatory regions in one organism (e.g., bacteria), but not in the plant are not ''genetic material necessary for the production of the pesticidal substance'' in the context of a plant-incorporated protectant. These sequences are not used in a living plant, or in the produce thereof.

Under the second scenario, a plant-incorporated protectant is introduced into a plant, but, because of constraints such as the plant's genetic background, or the point of insertion in the plant's genome, or accidents of insertion in which an incomplete copy of a gene is inserted or a regulatory element is lost, the pesticidal substance is never produced from the genetic material. In the absence of pesticidal claims, or other indicia of intent, the genetic material would not be considered part of a plant-incorporated protectant. If, however, in subsequent generations, the previously silent genetic material produces the pesticidal substance, and pesticidal claims or other indicia of pesticidal intent are present, the previously silent genetic material would be considered, along with the pesticidal substance, a plant-incorporated protectant.

b. *Will EPA need to know how many copies of a gene are introduced into a plant?* One commenter questioned whether a registrant would need to provide EPA with the number of copies of the genes that are introduced into the plant when seeking a registration, and whether a change in the number of copies present in the plant would trigger a new registration action.

The number of copies of the gene(s) introduced into the plant for the production of the pesticidal substance will not necessarily be a factor in EPA's determination of whether a new registration is needed. However, the amount of the pesticidal substance (i.e., levels of expression) in various plant tissues may be important for an assessment of potential exposure, and levels of expression may, in some cases, be related to number of gene copies. Thus, while, in general, changes in gene copy number would not automatically require an amendment to the registration, such information may, on occasion, be important in identification and management of risk. Currently, the Confidential Statement of Formula, containing information that must be submitted with each application for registration, describes either the range of levels of pesticidal substance(s) expected to be expressed in the plant, or a maximum level expected to be produced by the plant. Should the level of the pesticidal substance(s) be increased beyond, or decreased below, the range or the maximum level described in the Confidential Statement of Formula, EPA believes that the registrant would generally be required to submit an application for an amended registration pursuant to 40 CFR 152.44, as the risk assessment performed for levels listed in the Confidential Statement of Formula may not be relevant for the new levels. EPA may, in certain cases, waive this requirement, as described in 40 CFR 152.44(b)(1), or permit an applicant to modify a registration by notification or non-notification, in accordance with 40 CFR 152.46. Registrants are therefore encouraged to consult with the Agency in such cases. Distribution or sale of products containing levels beyond those described in the Confidential Statement of Formula may constitute an unlawful act under FIFRA section 12. This approach for plant-incorporated protectants is consistent with the Agency's approach for more traditional

pesticides (e.g., pesticides synthesized through petroleum chemistry) with regard to pesticide levels as described in the Confidential Statement of Formula.

c. *Will EPA need to know about changes in regulatory regions?* One commenter questioned whether changes in regulatory regions would affect the status of a registered product. For example, would a new registration be required if one promoter is substituted for another in an already registered plant-incorporated protectant?

Regulatory regions such as promoters are part of the definition of ''genetic material necessary for the production'' of a pesticidal substance. EPA does not anticipate that a new registration, or an amendment to the existing registration, would always be required with each modification to a regulatory region. However, EPA believes that in general, an application for an amended registration would need to be submitted pursuant to 40 CFR 152.44. Because the Agency has the discretion to waive this requirement, or to permit an applicant to modify a registration by notification or non-notification, registrants are encouraged to consult with the Agency to determine whether the Confidential Statement of Formula would need to be modified and consequently a new registration or an amendment to the existing registration would be required. In some cases a modification to a regulatory region could result in a new formulation, a new use, or a new active ingredient. For example, a change in a regulatory region could result in the pesticidal substance being expressed in a different plant tissue than where the pesticidal substance had been expressed for the original registration. In the assessment for the original registration, risk might only have been evaluated for production of the pesticidal substance in the leaves of the plant. With the change in promotor, the pesticidal substance could now be produced in the fruit, and risk would have to be evaluated for production of the pesticidal substance in the fruit. Evaluations to assess the potential for risk associated with such changes typically occur in a new registration action or an action amending an existing registration.

d. *How will EPA view enzymatic pathways?* Several commenters asked whether EPA would regulate genetic material encoding enzymatic pathways leading to the production of a pesticidal substance. Another comment noted that it ''is not clear from either the definition of active or an inert ingredient how or whether EPA intends to regulate novel gene products, and the genetic material necessary for their production, that represents substances such as enzymes, precursors, or intermediates in biosynthetic pathways that lead to the production of a pesticidal substance.''

With regard to the genetic material necessary for the production of the enzymes that are part of a pathway anabolizing the pesticidal substance, this genetic material is necessary for the production of the pesticidal substance, and thus, it is part of the plant-incorporated protectant.

With regard to the enzymes, precursors, or intermediates in biosynthetic pathways necessary for anabolizing the pesticidal substance, EPA at this time considers them to be part of the plant-incorporated protectant because the substance is intended to ''ensure the presence of the active ingredient''—i.e., it is an inert ingredient. Given that it is theoretically possible that at least some of these substances could be associated with greater potential for adverse effects than the actual substance acting as a pesticide (e.g., precursors could be more toxic to a nontarget species than the actual pesticidal substance), EPA has at this time adopted a prudent course. As the Agency gains greater experience, it may reconsider how it treats enzymes, precursors or intermediates in anabolic pathways introduced with the express purpose of producing a pesticidal effect.

iii. *What comments were received on the word ''living'' in the plant-incorporated protectant definitions?* Several comments suggested that the word ''living'' be deleted from the definition of plant-incorporated protectant because inclusion of that word in the definition of plant-incorporated protectant confused the status of pesticidal substances used for protection against pests post-harvest. For post-harvest control, a pesticidal substance may be produced in the plant during the growth portion of its life cycle, not for protection of the growing plant against pests, but for use during the post-harvest stage, e.g., to protect the seed or fruit during storage. Another comment asked for clarification of the status of exudates and materials that are active in intercellular spaces and/or apoplasts in light of the clause ''for use in the living plant.''

a. *What does the word ''living'' signify in the plant-incorporated protectant definitions?* EPA believes it is important to include the word, ''living'' in the definitions to distinguish plant-incorporated protectants from other types of pesticides. A pesticide is a plant-incorporated protectant only if the pesticide is intended to be produced and used *in situ* in the plant.

The characteristic of being produced *in situ* and used in the living plant makes plant-incorporated protectants unique, particularly with regard to exposure considerations. Exposure considerations for plant-incorporated protectants will be dependent to a large part on the biological characteristics of the living plant in which the plant-incorporated protectant is produced and used. For example, if a plant can outcross with nearby relatives, the potential for spread and increase in the environment of that plant-incorporated protectant through the spread of pollen must be evaluated.

Inclusion of the word ''living'' in these definitions serves to distinguish plant-incorporated protectants from other types of pesticides. For example, it distinguishes plant-incorporated protectants from pesticides like pyrethrum isolated from chrysanthemums and applied to other plants, or pesticides such as the powder, produced by drying and grinding cayenne peppers, dusted on plants with the intent of preventing, destroying, repelling or mitigating a pest. A pesticide that consists of a dead plant or a portion of a dead plant that is intended to be used to control pests is currently regulated under FIFRA as subject to 40 CFR parts 153 through 173 and 40 CFR parts 177 through 180. An example of such a pesticide is pyrethrum, isolated from a plant and applied topically to other plants.

Because of the importance of distinguishing plant-incorporated protectants from other types of pesticides, EPA will retain the term ''living'' in the definitions of plant-incorporated protectant and active ingredient. However, EPA agrees with the commenter that a pesticidal substance produced in the plant during the growth portion of its life cycle, not for protection of the growing plant against pests, but for use during the post-harvest stage, would still be for a pesticidal activity that should be treated by EPA as a plant-incorporated protectant and thus subject to 40 CFR part 174. EPA believes the 1994 **Federal Register** documents (59 FR 60496, 60519, 60535, 60542 and 60545) clearly indicates that this was EPA's intent. However, because EPA does not believe it appropriate to delete the term ''living'' from the definition of plant-incorporated protectant, the Agency clarifies its intent regarding post-harvest control by including the phrase, ''or in the produce thereof,'' in the definition of plant-incorporated protectant.

To reinforce the distinction between plant-incorporated protectants and other types of pesticides, the word ''living'' is

also added to the definition of recipient plant. Similarly, to emphasize that a plant-incorporated protectant is a pesticide produced and used *in situ* in a plant, a definition of ''pesticidal substance'' is added at 40 CFR 174.3 and 40 CFR 152.3.

To further clarify how EPA views a plant-incorporated protectant when the pesticidal substance is produced, or used, in perhaps only part of a plant's life cycle, EPA is including the phrase, ''during any part of the living plant's life cycle,'' in the definition of pesticidal substance. This phrase clarifies that, if a pesticidal substance is intended to be produced and used for preventing, destroying, repelling or mitigating a pest at any time in a plant's life cycle, the pesticidal substance and the genetic material necessary for the production of the pesticidal substance are considered a plant-incorporated protectant, even if the substance is not continually produced at detectable levels throughout all parts of the plant's life cycle, or intended to be used in every part of a plant's life cycle for preventing, destroying, repelling or mitigating a pest. For example, the pesticidal substance may not be produced in the seedling but is produced in the tissues of the mature plant for preventing, destroying, repelling or mitigating a pest. In this situation, the seedling would be considered to contain a plant-incorporated protectant, because the pesticidal substance is produced and used during at least one stage of the plant's life cycle. Further, the genetic material necessary for the production of the pesticidal substance, which itself falls within the definition of pesticide under FIFRA section 2(u), and is defined as part of the plant-incorporated protectant in this rulemaking, would be present during all phases of the plant's life cycle. Depending on the biology of the plant, the life cycle could include, for example, a seed, an embryo, a seedling, a mature or senescent plant.

EPA has broad authority to regulate a pesticide. For example, the Agency follows the fate of substances applied as pesticides in the soil after the harvest of the crop and during rotational crop plantings. This allows EPA, as required by FIFRA, to ensure that a pesticide does not cause unreasonable adverse effects even when the intent of preventing, destroying, repelling or mitigating a pest is not evident.

A plant's life cycle is considered to be one generation, such as a seed to seedling to a mature plant and back to a seed for sexually reproducing plant species, and a vegetative propagule to adult plant to vegetative propagule for plants reproducing asexually. As in the common understanding of the term (Ref. 5), a propagule is the part of an organism that may be disseminated and reproduce the organism.

b. *How does EPA view exudates and materials that are active in intercellular spaces and/or apoplasts?* One commenter requested clarification on the status of exudates and materials that are active in intercellular spaces and/or apoplasts. An apoplast is a cell wall continuum of a plant (Ref. 9). Materials that are active in intercellular spaces are those active between the cells of the plant (Ref. 9). Apoplasts and intercellular spaces are within the living plant. An exudate is composed of substances that were within a plant and were exuded from the plant, within one of the commonly understood meanings of the word exude; i.e.,''to give off gradually through pores'' (Ref. 5). EPA views apoplasts, intercellular spaces and exudates as properly being part of a living plant as described in the 1994 **Federal Register** document (e.g., see 59 FR 60534). EPA believes that this view of a living plant as the sum of its parts is evident in the preamble discussions of the November 23, 1994 policy (59 FR 60496) and proposed rule (59 FR 60519). In order to ensure that this view of the living plant is clear to the regulated community, EPA is adding at 40 CFR 174.3 a definition for the phrase, ''in a living plant,'' which is part of the definition of ''plant-incorporated protectant.'' The definition of ''in a living plant'' is intended to clarify that, for plant-incorporated protectants, the pesticidal substance is part of a plant-incorporated protectant when it is inside the living plant, on the surface of the living plant or an exudate given off gradually as part of a naturally occurring process by a living plant (Ref. 10). The term ''in a living plant'' is defined at 40 CFR 174.3 to mean ''inside the living plant, on the surface of the living plant, or as an exudate from the living plant.'' For the purposes of this rule, EPA defines an ''exudate'' as ''a substance gradually discharged or secreted across intact cellular membranes or cell walls and present in the intercellular spaces or on the exterior surfaces of the plant.'' EPA believes these actions address the commenter's request for clarification.

Sap or other material that is collected through mechanical means from a plant (e.g., sap exuded from a gash resulting from intentional wounding in the bark of a tree) by a human and sold or distributed as a pesticide does not fall within the definition of ''exudate'' because it was not given off gradually as part of a naturally occurring process from the plant. Rather it results from the wounding of the plant. Materials such as maple syrup may meet the definition of ''produce thereof'' if a substance within the syrup is intended to serve a pesticidal purpose by protecting the syrup after it has been collected from the tree. However, sap collected by mechanical means sold or distributed as a pesticide to protect some other produce or thing would be subject to regulations found in 40 CFR parts 150 through 173 and 40 CFR parts 177 through 180, rather than 40 CFR part 174.

iv. *What other modifications have been introduced into the definitions?* EPA, for purposes of clarity, introduces two other modifications to the plant-incorporated protectant definitions. First, EPA modifies the definition of ''plant-incorporated protectant'' for greater clarity, to include the concept of intention to use in a living plant as well as to be produced in a living plant, and to include the concept of the produce thereof, for similar reasons as discussed in Unit VII.B.8.iii.a. ''Produce thereof'' is defined to mean, when used with respect to plants containing plant-incorporated protectants only, a product of a living plant containing a plant-incorporated protectant, where the pesticidal substance is intended to serve a pesticidal purpose after the product has been separated from the living plant. Examples of such products include, but are not limited to, agricultural produce, grains and lumber. Products such as raw agricultural commodities bearing pesticide chemical residues, are not ''produce thereof'' when the residues are not intended to serve a pesticidal purpose in the produce.

Second, the definition of living plant at 40 CFR 174.3 and 40 CFR 152.3 is revised to read:

Living plant means a plant, plant organ or plant part that is alive, viable or dormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems, flowers and pollen.

v. *What is an inert ingredient for this type of pesticide?* EPA originally proposed to define inert ingredients for plant-incorporated protectants as ''any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient'' (59 FR 60521).

In this section, EPA focuses on selectable markers. EPA discusses other inert ingredients in Unit VIII.B.8.ii.d. Therefore, throughout this discussion,

EPA uses the phrases ''substances used to confirm or ensure the presence of a plant-incorporated protectant in a plant'' and ''selectable markers'' interchangeably. Selectable markers are genetic material introduced into the plant or plant cells concomitant with the genetic material that confers the desired trait (e.g., a pesticidal trait). A selectable marker provides a means of distinguishing and selecting plants or plant cells that have successfully incorporated the genetic material conferring the desired trait from the vast majority of plants or plant cells that have not. For example, the selectable marker may endow the recipient cell with the ability to resist a lethal agent and the selection process may depend upon the cells that acquired the introduced genetic material being resistant to the lethal agent. When the cells are exposed to the lethal agent, the cells that did not incorporate the genetic material are killed, while the cells that did incorporate the introduced genetic material survive. When the researcher uses the toxic agent to select those cells that can resist the lethal agent, the researcher also selects the cells that acquired the desired trait (e.g., a pesticidal trait).

In response to its proposed rule in 1994, EPA received several comments suggesting that plant-incorporated protectant inert ingredients that had been reviewed by FDA should be exempt from EPA review. One commenter, noting that the 1992 FDA policy statement (57 FR 22984) addresses the relevant food safety issues associated with selectable markers, suggested these should only be reviewed by FDA. Other commenters suggested that the genetic material necessary for the production of the pesticidal substance be defined as an inert ingredient for plant-incorporated protectant, along with selectable markers, rather than as an active ingredient. Yet other commenters suggested that EPA broaden its original proposed rule to include ''a substance used to assist in the identification of plants or plant cells containing the active ingredient.'' Another commenter suggested that marker genes and their products should be considered active ingredients in order to ensure some type of ''safety review'' of the marker genes. Another commenter urged EPA to make clear that plant-incorporated protectant inert ingredients are excluded from EPA's ''new inerts'' policy (52 FR 13305, April 22, 1987) which requires testing and EPA approval of inerts not already on the Agency's approved inerts list.

During development of the final rule, EPA reconsidered its 1994 proposed rule and published a supplemental document on July 22, 1996 in the **Federal Register** (61 FR 37891), discussing the Agency's treatment of inert ingredients. In the supplemental document, EPA discussed several considerations that argued against treating selectable markers as inert ingredients, including: the unique nature of plant-incorporated protectants and substances such as selectable markers; the function of selectable markers in plants; and the effects of selectable markers on the performance of the plant-incorporated protectant. The Agency pointed out that substances such as selectable markers are intentionally introduced into plants to aid in the selection of plants or plant cells that contain the desired genetic material necessary for producing the plant-incorporated protectant and consequently are typically introduced into the plant at the same time as the active ingredient (61 FR 37892–37893, July 22, 1996). Because the requisite intent to include such substances in the pesticide product is present in the use of selectable markers in plant-incorporated protectants, the markers would be considered to be an inert ingredient under the Agency's traditional interpretation of that term. But EPA also noted that selectable markers do not have pesticidal properties themselves, are not necessary for the plant-incorporated protectant to function in the plant and are usually used only once in the early stages of product development, and are of no use in modifying or enhancing the pesticidal activity of the plant-incorporated protectant. EPA also speculated that the marker genes could be lost from the plant during subsequent breeding with no effect on the active ingredient, and provided the public an additional opportunity to comment on how such substances should be viewed under FIFRA (61 FR 37893, July 22, 1996).

Many of the comments EPA received in response to the supplemental document recommended that selectable markers not be considered inert ingredients. Several of these commenters supported their recommendation by noting that it would reduce the ''potential for duplication with reviews by the FDA,'' which already reviews the food and feed safety of selectable markers. One commenter, who supported a decision not to consider all selectable markers as inert ingredients, nevertheless noted that the commenter was ''particularly concerned about adverse environmental impacts of such substances on non-target organisms, particularly salmon or members of aquatic ecosystems upon which their survival depends.'' Another commenter, while concurring that EPA should not regulate selectable markers as inert ingredients, suggested that EPA explore in greater detail the ramifications of using herbicide tolerant traits as selectable markers. This commenter was concerned that potentially widespread use of herbicide resistance traits as selectable markers ''may tempt unscrupulous farmers to apply the herbicide to crop plants in the field, even though the herbicide is not registered for use with the crop plant.''

To determine how to proceed, the Agency considered the comments received in response to both its original proposed rule and the supplemental document, and the degree to which they addressed the considerations laid out in the supplemental document. This included comments on the Agency's treatment of individual selectable markers, as well as the Agency's overall approach to inert ingredients. None of the comments, however, provided information or analyses that definitively resolved the question one way or another.

Although the majority of commenters supported a decision not to treat selectable markers as inert ingredients, most of these comments appeared to be based on concerns over the potential for duplicative oversight between EPA and FDA. In addition, several comments received in response to both notices raised human health and environmental safety issues surrounding certain selectable markers, such as genes coding for herbicide or antibiotic resistance, and supported some government oversight to ensure that a ''safety review'' was conducted.

With respect to the potential for duplicative oversight, EPA acknowledges that some degree of overlapping jurisdiction with FDA currently exists in that both agencies share responsibility for evaluating different aspects of a selectable marker. As previously explained, both agencies have agreed that EPA will address under its regulatory jurisdiction the food safety issues associated with the pesticide, including selectable markers. Any food safety questions beyond those associated with the pesticide, such as those raised by unexpected or unintentional compositional changes, are under FDA's jurisdiction (57 FR 22984 and 59 FR 60514).

Bearing in mind the concerns with respect to duplicative review, EPA considered whether relinquishing

jurisdiction to FDA would best address the health and safety concerns raised. Although many of the issues with respect to the safety of the food or the development of antibiotic resistance are within FDA's traditional purview and expertise, the issues with respect to impact on non-target organisms and ecosystems are ones with which EPA has greater experience in regulating under FIFRA. And given EPA's longstanding expertise in considering food safety concerns under the FFDCA, it was determined that on balance, the totality of the concerns could be better addressed by regulating under both FIFRA and the FFDCA than by regulating under the FFDCA alone. These considerations thus weighed in favor of considering selectable markers to be inert ingredients in a plant-incorporated protectant. Moreover, EPA and FDA can work together to minimize the impacts arising from any overlap in jurisdiction, and will coordinate extensively towards that end.

As EPA explained in the 1996 supplemental document, FIFRA and FFDCA contain only general definitions of the relevant terms. FIFRA section 2(u) defines a ''pesticide'' as any substance or mixture of substances intended ''for preventing, destroying, repelling, or mitigating any pest'' or ''for use as a plant regulator, defoliant, or desiccant'' or ''any nitrogen stabilizer (7 U.S.C. 136(u)).'' An ''active ingredient'' is defined as ''in the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest'' (7 U.S.C. 136(a)). FIFRA defines ''inert ingredient'' to mean ''an ingredient which is not active'' (7 U.S.C. 136(m)). Under the FFDCA, a substance is a ''pesticide chemical'' if it is ''a pesticide within the meaning of [FIFRA], including all active and inert ingredients of such pesticide'' (21 U.S.C. 321(q)(1)).

Although the statutory definitions provide some guidance, they do not definitively resolve whether the Agency should define substances intentionally introduced into the plant with the active ingredients as inert ingredients. EPA's current pesticide regulations, along with EPA's past practice and interpretation of those regulations, however, although not specifically addressing selectable markers, do provide considerable insight into the issue of inert ingredients. EPA's longstanding regulatory definition of ''inert ingredient'' includes as an inert ''any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product'' (40 CFR 152.3(m); see also 40 CFR 158.153(f)). A ''pesticide product'' is defined by regulation to be ''a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold'' (40 CFR 152.3(t)).

These definitions capture as inert ingredients, all those substances that are intentionally included in the pesticide product that are not active. Further, EPA has consistently interpreted these definitions to include substances that serve no useful purpose in the product. The Agency has never required that inert ingredients have pesticidal properties themselves, nor has the Agency required that inert ingredients modify or enhance the pesticidal activity of the pesticide although inert ingredients are often used for at least one of these purposes. In fact, the Agency has indicated on several occasions that inert ingredients are generally not ''pesticidally active'' (See, e.g., Inert Ingredients in Pesticide Products; Policy Statement, (52 FR 13305, April 22, 1987); see also Pesticide Registration Procedures; Pesticide Data Requirements, (53 FR 15952, 15963, May 4, 1988)). Thus, the essential criterion that the Agency has used to determine whether an ingredient is an ''inert'' is the intent of the producer to include the substance in the pesticide product.

In the case of plant-incorporated protectants, the Agency has emphasized in both the 1994 proposed rule and the 1996 supplemental document that substances ''such as selectable markers are intentionally introduced into plants'' (61 FR 37892–37893; see also 57 FR 60521). In the 1996 supplemental document, the Agency pointed out that substances such as selectable markers are intentionally introduced into plants to aid in the selection of plants or plant cells that contain the desired genetic material necessary for producing the plant-incorporated protectant and consequently are typically introduced into the plant at the same time as the active ingredient (61 FR 37892–37893). Because the requisite intent to include such substances in the pesticide product is present in the use of selectable markers in plant-incorporated protectants, the markers would be considered to be an inert ingredient under the Agency's traditional interpretation of that term. No commenters provided information or analyses that would contradict this interpretation or that would lend support to the other considerations laid out in the 1996 notice arguing against treating these markers as inert ingredients.

Moreover, since the 1994 proposed rule and 1996 supplemental document, EPA has had experience with selectable markers in the registration of several plant-incorporated protectants that is relevant to the considerations presented in the 1996 supplemental document. For example, contrary to the speculation in the 1996 document, some selectable markers are not used only once, i.e., to distinguish the cells transformed with the pesticidal trait from those that had not acquired the trait. Rather, the ability to resist the lethal agent is being used during the breeding process to develop commercially viable lines as a phenotypic identifier to select progeny plant lines having the desired pesticidal trait. In such cases, the role played by the selectable marker is somewhat different than was considered in 1996. In addition, in the interim, EPA has become aware of other substances that could be used as selectable markers, e.g., green fluorescent protein (Ref. 11), and while EPA can make some prediction about the potential interactions with and effects on the pesticidal substance of currently used selectable markers, e.g., antibiotic and herbicide resistance, it cannot do so for selectable markers that may be developed and used in the future.

In light of this experience, and in light of the concerns raised by some of the commenters regarding safety issues associated with the use of selectable markers, the Agency believes it prudent to consider these substances to be inert ingredients and to continue to assess their safety. EPA believes that these considerations outweigh the considerations discussed in the 1996 supplemental document, arguing against treating such substances as inert ingredients. Moreover, to ensure that health and safety issues are addressed by the Agency with the greatest technical expertise without duplicative oversight, EPA and FDA will work closely to address areas of potentially overlapping jurisdiction, and to share expertise in reviews. Consequently, for these reasons, as well as for the reasons outlined in the 1994 proposed rule, the Agency has determined that it will adopt the definition it proposed in 1994 with minor modification.

One comment asked whether EPA intended to treat the enzymes leading to the production of the pesticidal substance as inert ingredients. As noted in Unit VII.D.8.ii.d., EPA will consider the enzymes, precursors, or intermediates in biosynthetic pathways necessary for anabolizing the pesticidal

substance to be an inert ingredient of the plant-incorporated protectant.

One comment suggested that in ''anticipation of inerts that would be introduced to perform other nonpesticidal functions, the restrictive language should be removed and the relationship to the active ingredient characterized as intentionally introduced into a living plant in association with the active ingredient.'' EPA disagrees. The commenter's suggested language is so broad that it would cover introduced genetic sequences that EPA considers to be appropriately within USDA's or FDA's sphere, e.g., modifications to the starch content of a potato. As noted in the preceding paragraph, EPA anticipates that as it gains experience, it may change its view of what is appropriately an inert ingredient for plant-incorporated protectants, although the Agency does not anticipate that it would subsume in its definition all modifications affecting substances that have traditionally been in USDA's or FDA's purview. EPA acknowledges that any modification of the definition of inert ingredient for plant-incorporated protectant would be made through rulemaking.

With regard to the comment urging EPA to make clear that plant-incorporated protectant inert ingredients are excluded from EPA's ''new inerts'' policy (52 FR 13305), EPA has created 40 CFR part 174, subpart X, specifically for inert ingredients for plant-incorporated protectants. Inert ingredients in 40 CFR part 174, subpart X, are not part of EPA's ''new inerts'' policy (52 FR 13305) per se; however EPA's approach for plant-incorporated protectants is consistent with the policy.

Several commenters requested that EPA consider the genetic material necessary for the production of the pesticidal substance to be an inert ingredient. For reasons described in Unit VII.B.8.i., EPA will not consider this genetic material to be part of the inert ingredient.

C. Clarification of Exemption at 40 CFR 152.20; Status of Plants Used as Biological Control Agents with Regard to FIFRA Requirements

Most comments supported EPA's proposal to clarify that, although plants used as biological control agents will remain exempt under 40 CFR 152.20, plant-incorporated protectants will not fall within that exemption, but will be subject to FIFRA requirements, including the regulations codified at 40 CFR part 174. However, some commenters argued that the ability to resist pests is a characteristic of the plant and should not for regulatory purposes be separated from the plant itself. Another comment opposed exempting plants from FIFRA requirements and argued that the definition of biological control agent at 40 CFR 152.3 does not apply to plants. This commenter argued that the definition at § 152.3 was meant to apply to classical biological control agents—predaceous and parasitic arthropods—whose sole use is to control pests. The commenter further argued that plants cannot be considered classical biological control agents because the primary use of plants is not pest control but yield of a product; pest control for plants is merely an attribute which helps to achieve yield.

With regard to the comment concerning ''classical biocontrol agents,'' EPA recognizes that classical biocontrol generally involves the use of one organism such as a predaceous or parasitic arthropod to protect another organism such as a plant (Refs. 10 and 12). Plants were not specifically addressed in the regulation EPA published in the June 2, 1982, **Federal Register** document (47 FR 23928) that exempted, under FIFRA section 25(b)(1), most biological control agents from the requirements of FIFRA. There are, however, circumstances in which plants are used as ''classical'' biological control agents analogous to the use of predaceous and parasitic arthropods to protect other organisms. For example, organic gardeners use living plants, such as marigolds, chrysanthemums and geraniums, in their gardens with the intent of protecting other plants, such as vegetable plants. This type of plant for this type of use clearly meets the 40 CFR 152.3 definition of biological control agent because it is a ''living organism applied to or introduced into the environment that is intended to function as a pesticide against another organism declared to be a pest by the Administrator.''

Plants, when humans intentionally use them for preventing, destroying, repelling or mitigating a pest, meet the FIFRA section 2(u) definition of pesticide, and thus are pesticides. A living plant that is intended to have a pesticidal effect meets the definition at 40 CFR 152.3 of biological control agent because it is a ''living organism applied to or introduced into the environment that is intended to function as a pesticide against another organism declared to be a pest by the Administrator.'' In 1994, EPA advised the public that the Agency considered plants that protect themselves against pests to fall within the definition of biological control agents (59 FR 60496). This statement created some uncertainty regarding the regulatory status of such plants under FIFRA, in part because such plants were not explicitly addressed in the preamble to either the proposed or final rule establishing the exemption at 40 CFR 152.20 (46 FR 18, 322, March 24, 1981; 47 FR 23928, June 2, 1982). Today's action clarifies the status of such plants. The plants themselves will remain exempt, but EPA will continue to regulate the pesticidal substances in such plants under FIFRA and the FFDCA, even when they are intended to be used in the exempt plants.

Moreover, the commenter fails to provide any meaningful distinction between ''predaceous and parasitic arthropods whose sole use is to control pests'' and plant-incorporated protectants. All agricultural use pesticides are, in some sense, applied to crops to increase yields, or to otherwise obtain the maximum profit from the crop. It has been EPA's experience that farmers do not apply pesticides simply to kill insects without also intending to affect yield, or to otherwise protect or increase a crop's profitability.

EPA also disagrees with the comment that, for regulatory purposes, a characteristic of the plant should not be separated from the plant itself. EPA believes that its decision to regulate plant-incorporated protectants, while exempting the plants themselves is an appropriate regulatory approach because it allows the Agency to focus its oversight on the ''pesticidal'' characteristics of the plant, and any associated risks. In addition, this approach is consistent with the Agency's long-standing regulation under FIFRA.

Under existing regulations, although the plant itself is exempt from FIFRA requirements, substances that are extracted from plants and used as pesticides are not similarly exempted. For example, chrysanthemums produce pyrethrum, a substance that has insecticidal activity. Chrysanthemums that produce pyrethrum are exempt from regulation when used as biological control agents (i.e., living chrysanthemums), but pyrethrum itself as the pesticidal substance, is not exempt when it is extracted from chrysanthemum plants and applied to other plants as a pesticide. This distinction is reasonable in light of the potential for increased and unique exposures due to large-scale application of extracted pyrethrum to plants that do not naturally produce it. The use of extracted pyrethrum as an insecticide can involve exposure to the pesticide over large acreage, whereas the exposure

associated with pyrethrum produced by living chrysanthemum plants would not be expected to reach such proportions. In addition, application of pyrethrum beyond the environment in which it is naturally produced (i.e., beyond the living chrysanthemum plant) could result in new or unique exposures of nontarget organisms, including humans.

With the development of modern biotechnology, the number of such plants sold with the intention that the pesticidal substances in the plant function while in the plant, rather than extracting the pesticidal substance from the plant, have dramatically increased. But of greater regulatory significance, with these techniques, a plant can be endowed with properties that were previously not possible; for example, the ability to produce pyrethrum can be given to a crop plant such as corn. Different exposure considerations would exist for pyrethrum in corn than for pyrethrum in chrysanthemums. Given that millions of acres are planted to corn in the US, some of the exposure considerations of pyrethrum in corn might be more analogous to the considerations for exposure from sprayed pyrethrum than to considerations for pyrethrum in chrysanthemums.

Similarly, potato, cotton and corn plants have recently been engineered to produce the endotoxin from the bacterium, *Bacillus thuringiensis* (Bt). EPA assessed the risk of these Bt-based plant-incorporated protectants in a manner consistent with EPA's treatment of Bt in other formulations. Bt is regulated under FIFRA when formulated in products to be dusted/sprayed on plants for protection against pests. Many of the risk considerations evaluated for Bt used as a plant-incorporated protectant are the same considerations evaluated for Bt sprayed or dusted on plants as a pesticide.

In this final rule, EPA clarifies that plants that humans use with the intention of controlling pests will remain exempt from FIFRA requirements pursuant to the exemption at 40 CFR 152.20, but that the pesticidal substances, and inert ingredients contained in the plants, remain subject to the requirements of FIFRA, as codified at 40 CFR part 174. The regulatory text at § 152.20 is also modified to make clear that the exemption for plants used as biological control agents applies to living plants and does not apply to plants or plant parts that have, for example, been dried or processed for use as pesticides. An example of this latter type of pesticide would be the powder, produced by drying and grinding cayenne peppers, dusted on plants with the intent that it would protect the plants against disease. This type of pesticide does not meet the definition of biological control agent and is not exempted at § 152.20. Processed plants or plant parts used as pesticides are currently subject to the regulations at 40 CFR parts 150 through 173 and 40 CFR parts 177 through 180.

EPA believes it is appropriate to exempt the living plant from FIFRA requirements. The Agency believes its focus on the plant-incorporated protectant rather than on the plant allows it to ensure a low probability of risk to humans and the environment, while imposing a minimum burden on the development of plants containing novel plant-incorporated protectants and conserving limited Agency resources. Had EPA chosen to regulate the plant, it would have issued registrations for plant varieties. By focusing on plant-incorporated protectants, in contrast, EPA can issue a registration for use of the plant-incorporated protectant within a larger grouping, such as a crop. This allows the Agency to focus its resources on evaluating the pesticidal properties of the plant, rather than on other properties of the plant. EPA believes that the clarification in this rule today that it will not regulate plants per se, and the exemption it is issuing today in another section of this document, and in a companion document published elsewhere in this issue of the **Federal Register**, limit EPA's effect on plant breeding and allow most aspects of plant breeding to be pursued without EPA regulation.

However, EPA also believes it is appropriate to exclude certain plant-incorporated protectants from the exemption at 40 CFR 152.20. Section 25(b) requires the Agency to support its determination that a class of pesticides meet the standard for an exemption. EPA's assessment supporting the 1982 exemption did not encompass all of the plant-incorporated protectants being developed and marketed today, and the Agency could not rely on those assessments to support such an exemption. As noted above, with modern biotechnology, a plant can be endowed with properties that were not possible in 1982, and different exposure and hazard considerations would exist for such plants. Nor could the Agency develop sufficient evidence to maintain a categorical exemption for all plant-incorporated protectants, given all of the possible genetic modifications that can be achieved with these techniques, even if the Agency were inclined to do so. As an initial matter, Agency could not anticipate all potential modifications, let alone develop a risk assessment for all potential intended, and unintended, effects from such modifications.

EPA is exempting those plant-incorporated protectants for which the Agency can support the necessary findings, based on the available scientific evidence and the Agency's technical expertise. For example, the exemptions established in another section of this document, and in a companion document published elsewhere in this issue of the **Federal Register**, encompass the chrysanthemum discussed above, as long as it meets the exemption criteria, even though it contains a plant-incorporated protectant. As the Agency's base of knowledge and experience increases, exemptions for additional categories of plant-incorporated protectants may be warranted. But until then, the Agency believes that a case-by-case review of plant-incorporated protectants not specifically exempted in this rule, is necessary to ensure that such products can be sold and used without generally posing unreasonable adverse effects on the environment. Case-by-case review will also allow the Agency to increase the available body of scientific knowledge and experience to determine whether additional exemptions are warranted. In addition, any person may petition EPA to establish an exemption pursuant to FIFRA section 25(b) and FFDCA section 408(d). EPA encourages additional exemptions when supported by scientific data and will make every effort to expedite its review of such petitions, consistent with the requirements of these sections.

D. Exemption of Plant-Incorporated Protectants Derived Through Conventional Breeding from Sexually Compatible Plants

This rule exempts from FIFRA requirements, except for the adverse effects reporting requirements at 40 CFR 174.71, plant-incorporated protectants derived through conventional breeding from sexually compatible plants.

In 1994, EPA proposed to exempt from all FIFRA requirements, except for the adverse effects reporting requirements now at 40 CFR 174.71, a category of plant-incorporated protectants based on the premise that new exposures would be unlikely if the genetic material leading to the production of the plant-incorporated protectant is derived from a plant closely related to the recipient plant. EPA offered three options for defining plant-incorporated protectants derived from plants closely related to the recipient plant. All of the options were

based on the concept of source organism and the phylogenetic relatedness of the genetic donor and recipient. None of the three options was based on the process by which a plant-incorporated protectant was introduced into the recipient plant. Option 1, based upon sexual compatibility, was EPA's preferred option (59 FR 60534). Under this option, plant-incorporated protectants derived from plants sexually compatible with the recipient plant would be exempt from FIFRA regulation. Options 2 and 3 used taxonomy (genus) to define closely related plants, either exclusively (Option 2) or in conjunction with sexual compatibility (Option 3). The Agency also requested comment on the utility of an exemption criterion based on the process (e.g., rDNA) used to introduce the plant-incorporated protectant into a plant (59 FR 60514 and 60530). This approach was discussed by the SAP Subpanel and BSAC Subcommittee at the joint meeting of these scientific advisory groups held on January 21, 1994. In this approach, plant-incorporated protectants developed through techniques other than those of modern biotechnology would be exempted, e.g., those developed through conventional plant breeding would be exempted. Categories of those plant-incorporated protectants that were not exempted by this criterion could subsequently be considered for exemption on the basis of risk potential.

The joint subcommittee/subpanel report recommended such a ''process-based'' approach on the following three considerations. First, the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules established a precedent that has worked well. Second, although new techniques, such as rDNA, are more precise than conventional plant breeding, it is possible to make with rDNA novel genetic modifications never before possible. The novel combinations possible with modern genetic techniques create uncertainties about how the gene will function and how its products may affect the plant's phenotype and its impact upon the environment and human health. Third, establishing rDNA methodologies as a criterion for oversight may give the public more confidence that risk potential is being evaluated. As a result, approved products may move to the marketplace more easily (Ref. 15).

The majority of the comments on the proposed exemption based on the degree of relatedness between the donor and recipient plants favored the option based on sexual compatibility between the donor and recipient plants (preferred option in the November 23, 1994 **Federal Register** document (59 FR 60533)). The Agency did not receive any comments that favored the option based on taxonomy, Option 2. Although several comments favored the option that relied on both taxonomy and sexual compatibility, Option 3, EPA also received comments that expressed reservations about using taxonomy to describe a close degree of relatedness for regulatory purposes.

EPA received numerous comments supporting an approach based on process, i.e., that those plant-incorporated protectants introduced by rDNA would be regulated. The arguments advanced by these commenters can be represented by the comment that:

> genetic engineering (particularly recombinant DNA [rDNA] methodologies), represent a fundamental technical advance over traditional plant breeding in the ability to manipulate plants genetically. Genes which code for production of plant-pesticides can be readily turned 'on' or 'off' to dramatically increase the existing levels of plant-pesticides within plants, turning plants into pesticide factories and delivery systems. . . . given the fact that rDNA technologies represent such a fundamental technical advance over plant breeding, and given that plant-pesticides are by their very nature toxic substances, all plant-pesticides produced via rDNA methodologies should undergo some form of review under both FIFRA and FFDCA . . . . (Ref. 13).

Several letters described quantitative changes in the levels of plant-incorporated protectants as specific instances in which the commenter believed risk would be better addressed by an approach based on process.

Some comments urging regulation based on whether rDNA had been used to introduce the plant-incorporated protectant supported exempting conventional breeding. One commenter, for example, stated that pesticidal products that ''are introduced by traditional breeding pose generally low risk and should be exempt'' (Ref. 14).

Based on the advice of the BSAC and SAP at the joint meeting held January 21, 1994, and the comments received in response to the November 23, 1994 **Federal Register** document, EPA has determined that it is appropriate to issue a limited exemption for those plant-incorporated protectants derived through conventional breeding from plants sexually compatible with the recipient plant. In a companion document published elsewhere in this issue of the **Federal Register**, EPA solicits public comment on alternate options for the category of plant-incorporated protectants derived through modern biotechnology, e.g., rDNA techniques, from plants sexually compatible with the recipient plant. The Agency is considering these options in response to the public comment received on its earlier proposals. One of these options would establish notification procedures, and as the public has not had an opportunity to comment on either the procedures themselves, or the criteria on which EPA would base its regulatory decisions, the Agency believes it is appropriate to seek additional public comment prior to adopting a particular option. In addition, as these alternatives would distinguish between categories of plant-incorporated protectants based solely on the processes by which they are derived, the public will also have an opportunity to present additional comments on whether this is an appropriate distinction for regulatory purposes.

1. *What is the language of the exemption?* In this action, EPA is exempting only a subgroup of the category it proposed to exempt in 1994, those plant-incorporated protectants derived through conventional breeding from sexually compatible plants.

i. *Why is sexual compatibility an appropriate standard?* EPA believes sexual compatibility is an appropriate standard because sexually compatible plants share a common pool of genetic material, even though there may be some variability among plants in sexually compatible populations. Sexual compatibility, the ability to produce viable offspring, is only possible in nature for plants that possess many traits in common. Traits, and the genetic material encoding them, can be passed through sexually compatible plant populations by hybridization, and the mixing of genetic material that occurs through this process of mating tends to a situation where the members of sexually compatible population have similar traits and similar genetic material. This is particularly true with crop plants where generations of selection and breeding have tended to decrease the total genetic variability in many agronomic species. Sexually compatible thus presents a natural grouping of plants which can be readily described and used as a regulatory standard, and about which a large amount of information exists in the scientific literature. This information can be used in assessing risk.

Using sexual compatibility as a standard affords a clear delineation of whether a plant-incorporated protectant meets the conditions of the exemption. In most cases, whether two plants are sexually compatible is known; thus, testing to determine whether the plants

are sexually compatible is not likely to be necessary. If, in rare cases, it is not known whether two plants are sexually compatible, the means of determining sexual compatibility is straightforward and simple. Sexual compatibility is empirically demonstrable. EPA believes that the criterion of sexual compatibility provides a high level of regulatory clarity and the greatest ease of implementation, while at the same time presenting the lowest probability of novel dietary exposure. This standard allows the public, industry, and EPA to easily and readily identify those plant-incorporated protectants that meet the criterion of being derived from plants closely related to the recipient plant.

a. *Why is sexual compatibility limited to conventional breeding?* As explained in a companion document published elsewhere in this issue of the **Federal Register**, EPA is soliciting additional comment on the various options it is considering in response to the significant comments it has received raising issues specific to plant-incorporated protectants derived through genetic engineering. Because none of the comments raised significant issues relative to plant-incorporated protectants derived through conventional breeding, the Agency is finalizing its proposals with respect to this subgroup of products. Therefore, EPA includes in the definition of sexually compatible at 40 CFR 174.3 the clause ''through conventional breeding.'' EPA also provides a definition of conventional breeding that equates it to the creation of progeny through either: The union of gametes, i.e., syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses; or vegetative reproduction. Conventional breeding does not include use of any of the following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion. EPA believes that this definition addresses the recommendation of the SAP/BSAC at the January 21, 1994 joint meeting that ''the Agency define methodologies in a way that clearly delineates to the scientific community and the public what is and is not included in the regulatory scope'' (Ref. 15).

In the 1994 proposed rule (59 FR 60524) EPA states that its proposed rule is based on ''experience with the exposure of human populations to crops developed through the breeding process, i.e., crops developed through 100 years of scientific breeding among sexually compatible plant populations using Mendelian genetics.'' In its 1994 proposed rule, EPA calls this type of breeding, ''traditional breeding'' (see e.g., 59 FR 60519). When the Agency determined that it would exempt a subgroup of plant-incorporated protectants in the sexually compatible grouping while allowing additional comment on how EPA should treat those plant-incorporated protectants introduced into the plant through the techniques of modern biotechnology, EPA chose to describe the exempt group in the most straightforward manner; i.e., those derived through breeding. Recognizing that many consider the modern techniques of biotechnology as simply an extension of breeding techniques, EPA determined that an adjective was needed to modify the word ''breeding'' to adequately describe the exempt group. Although the Agency used the word ''traditional'' in its 1994 proposed rule, EPA chose the word ''conventional'' to describe this type of breeding in this rule because the SAP/BSAC in their report of the January 21, 1994, joint meeting used the adjective ''conventional'' in its advice to EPA (Ref. 15), and the word ''conventional'' might more readily connote techniques such as wide crosses.

b. *Why is conventional breeding described by processes such as pollination and vegetative reproduction?* One comment received on the 1994 proposed rule suggested that there is ambiguity in the proposed regulatory language at 40 CFR 174.5(a) in the November 23, 1994, **Federal Register** document (59 FR 60535) about whether plant-incorporated protectants that are ''native'' to a food crop would meet the criteria of exemption.

Because of the use of the word ''food'' in the comment, it was not clear whether the comment is directed toward EPA's proposed exemption under FIFRA or that under FFDCA for residues of plant-incorporated protectants derived from sexually compatible plants. EPA assumes this comment is directed at both exemptions, and that the commenter's suggestion is that EPA ensure that the regulatory language exempts from FIFRA requirements, those plant-incorporated protectants that normally occur in a plant (i.e., are ''native'' to the plant) and will be used in that plant. For example, if corn normally produced a plant-incorporated protectant, the regulatory text should be clear that the plant-incorporated protectant would be exempt when produced and used in corn. EPA believes inclusion of the word ''pollination'' as an example of a process leading to syngamy in the definition of conventional breeding addresses this concern. Pollination, the transfer of pollen from an anther to a stigma (Ref. 9), is the process through which traditional breeding with most angiosperms, i.e., most major crop plants, occurs (see e.g., 59 FR 60537) (Ref. 9). Inclusion of the word ''pollination'' in the definition emphasizes that plant-incorporated protectants that occur naturally in a plant growing from a viable zygote that arises by the mating in conventional breeding of one corn variety with another, or the mating of a corn plant with a corn plant of the same variety are exempt.

EPA recognizes that this same concern of ambiguity also applies to plant-incorporated protectants in plants that are propagated vegetatively. EPA believes inclusion of the phrase ''vegetative reproduction'' in the definition of conventional breeding addresses this concern. The language of the exemption for plant-incorporated protectants derived through conventional breeding from plants sexually compatible with the recipient plant specifically exempts plant-incorporated protectants in plants reproduced vegetatively. For example, plant-incorporated protectants in a plant propagated only vegetatively, (e.g., bananas), are exempt. Also exempt are plant-incorporated protectants in a plant propagated primarily vegetatively (e.g., potatoes), as long as, under conditions of reproduction through hybridization, the plant donating the genetic material is sexually compatible with the recipient plant as defined in at 40 CFR 174.3, and the other conditions described at subpart B, in particular 40 CFR 174.25, are met. Inclusion of the term vegetative reproduction in the definition of conventional breeding reflects EPA's statement in the 1994 proposed rule (59 FR 60524) on the status of crop plant varieties propagated vegetatively.

c. *Will wide and bridging crosses be part of the definition of conventional breeding?* In this final rule, EPA is implementing a definition of ''sexually compatible'' that includes wide and bridging crosses. In this final rule, wide crosses means to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre-pollination and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture or ovary and ovule cultures.

Generations of artificial hybridizations through these techniques have taken place in the well-established practices of plant breeding (Ref. 7). Wide crosses have been in the past, and are currently, commonly used to expand the plant gene pool for varietal improvement (Ref. 7), and a history of safe use has been associated with plant varieties developed through the use of wide cross techniques (Ref. 7). A fairly high degree of relatedness between the parental plants is indicated when a wide cross produces a viable zygote. This high degree of relatedness indicates a low probability of new exposures.

The definition of ''bridging crosses between plants'' is intended to convey the concept that an intermediate plant could be used in a cross to move traits from a source plant into a desired recipient plant. The intermediate plant can form viable zygotes with both the source and recipient plants, whereas the source and recipient plant cannot form viable zygotes. The intermediate plant serves as a bridge for gene flow between the two incompatible plants. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote. No comments were received on the proposed definition of bridging crosses between plants, also part of the definition of conventional breeding for sexually compatible. EPA is adopting this definition as proposed.

d. *Will cell or protoplast fusion be part of the definition of wide crosses?* EPA received one comment suggesting that protoplast fusion should be included in the definition of wide crosses between plants. In the technique of protoplast fusion, protoplasts are made in the laboratory through the removal of the cell walls of somatic cells. A somatic cell is a type of cell that forms plant vegetative tissues and organs and is distinguished from a germ cell which undergoes meiosis to produce reproductive tissues (e.g., pollen and egg cells). In the technique of protoplast fusion, protoplasts are made from the somatic tissue of two different plants. The membranes of the different protoplasts are then fused together mechanically through processes such as treatment with polyethylene glycol, producing a hybrid somatic cell with a genetic make-up resulting from the combination and sorting of the two plant genomes. The somatic hybrid cell is then grown on specialized media into a mature plant.

In support of the request, the commenter argued that the hybridization of somatic cells has a history of use to artificially induce sexual compatibility. The commenter argued that movement of genetic material by this means has historically been considered safe.

EPA did not, in its 1994 proposed rule include protoplast fusion in the definition of wide crosses between plants, nor did it perform an analysis of the potential for new exposures when protoplast fusion is used to perform wide crosses between plants. The commenter did not provide such information in response to the 1994 proposed rule nor the 1997 supplemental document. EPA does not believe information currently in the record supports inclusion of protoplast fusion in the definition of wide crosses. Therefore, EPA does not in this rule include protoplast fusion in the definition of wide crosses, and specifically excludes cell fusion from the definition of conventional breeding. However, EPA requests comment on whether protoplast fusion should be included in the definition of wide crosses in a supplemental document published elsewhere in this issue of the **Federal Register**. EPA would welcome submission of information on protoplast fusion. If the Agency obtains sufficient information demonstrating a low probability of risk, EPA may initiate notice-and-comment rulemaking under FIFRA section 25(b) and FFDCA section 408 to include protoplast fusion in the definition of wide crosses between plants.

e. *''Recombinant DNA'' and genetic material ''extracted from an organism and introduced into the genome of the recipient plant.''* As explained previously, EPA restricted this exemption to conventionally bred plant-incorporated protectants while the Agency solicits additional comment on the alternatives it is considering in response to the comments received on the 1994 proposal. Thus, in order to fully describe which plant-incorporated protectants are exempt under this exemption, EPA includes limiting phases. EPA in the 1994 **Federal Register** document (59 FR 60529) discussion of the advice of the SAP and BSAC at the January 21, 1994 meeting on the use of a process-based criterion to define a category of plant-incorporated protectants that would be subject to review, stated that the Agency would define such a process-based criterion in the following way: ''The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is extracted from an organism and introduced into the genome of the recipient plant or is synthesized *in vitro* and introduced into the genome of the recipient plant.'' In this action, EPA uses the language it put forth in the 1994 **Federal Register** document (59 FR 60529) to fashion two of the exclusions from the conventional breeding definition at 40 CFR 174.3. One exclusion is for techniques involving genetic material that has been extracted from the source and introduced into a recipient plant. Processes such as micro-injection, macro-injection and micro-encapsulation would be excluded from the conventional breeding exemption because they are used to introduce such extracted genetic material into the recipient plant. These processes have been included in the definition as examples to assist in understanding the concept.

The second exclusion from the conventional breeding exemption uses the term ''recombinant DNA'' to represent the concept of ''extracted from an organism. . ., synthesized *in vitro* and introduced into the genome of the recipient plant.'' To provide greater technical accuracy, EPA provides a definition at 40 CFR 174.3 for recombinant DNA as follows:

> *Recombinant DNA* means the genetic material has been manipulated *in vitro* through the use of restriction endonucleases and/or other enzymes that aid in modifying genetic material, and subsequently introduced into the genome of the plant.

ii. *Why is the concept of ''functionally modified from the source'' important and how does the definition of conventional breeding address it?* In the November 23,1994 **Federal Register** document (59 FR 60524), EPA explained that in proposing the exemptions the Agency did not intend to exempt a plant-incorporated protectant that is significantly different in structure or function from a plant-incorporated protectant as it occurs in the source. EPA believed this limitation was appropriate because rearrangements or modifications of the genetic sequence encoding a pesticidal substance made through the use of techniques such as rDNA could, for example, result in a plant-incorporated protectant with significantly different functions from the functions in the source plant. For example, if the pesticidal substance is an enzyme, it could be modified so that it acts on a different substrate in the recipient plant than it did in the source plant (Refs. 7 and 16). Such a significantly modified plant-incorporated protectant would not necessarily present risks similar to the substance prior to modification, nor would the base of experience on which EPA relies for support of the exemption necessarily be relevant. If the genetic material encoding the pesticidal

substance has been modified in such a way that the pesticidal substance functions differently in the recipient plant than it did in the source plant, the analysis performed to determine that the plant-incorporated protectant 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, would not apply.

In this final rule, this concern is addressed by the limitation placed on the definition of sexually compatible. Under this definition, plant-incorporated protectants derived from plants sexually compatible with the recipient plant are only exempt if they are introduced into the plant through conventional breeding as defined at 40 CFR 174.3. The types of changes discussed above (Refs. 7 and 16) that can be made through modern molecular techniques, are very unlikely to be made through conventional breeding as defined at § 174.3, and plant-incorporated protectants modified through modern molecular techniques are not eligible for this exemption.

iii. *Why is the phrase ''never derived from source not sexually compatible with recipient plant'' important?* EPA discussed the relevance of this phrase to the exemption in the November 23, 1994 **Federal Register** document (59 FR 60523). The phrase, ''has never been derived from a source that is not sexually compatible with the recipient plant,'' which is part of the language of the exemption at 40 CFR 174.25, was meant to clearly indicate that a plant-incorporated protectant would not qualify for the exemption if the genetic material introduced into a recipient plant is from a sexually incompatible source and then this recipient plant subsequently used to move the introduced genetic material into plants sexually compatible with this first recipient plant. For example, the exemption does not extend to a situation where the genetic material encoding the *Bacillus thuringiensis* delta endotoxin is introduced into wheat, and the endotoxin-producing wheat is subsequently hybridized with rye using wide cross techniques to produce triticale. The endotoxin produced in the triticale would not be eligible for the exemption because the genetic material encoding the endotoxin originated from a bacterium, a source that is not sexually compatible with the original recipient plant (wheat in this example).

EPA received a comment that suggested that the Agency delete this phrase from the regulatory text and instead include a period of time after which a plant-incorporated protectant would be treated as part of a plant's ''accessible'' gene pool. EPA does not accept the suggestion to delete this phrase from the regulatory text, and continues to include this language in the final rule at 40 CFR 174.25. EPA will not implement the commenter's suggestion that a gene, derived from a phylogenetically distant source and successfully used in a crop, be treated after a period of time as though it had become part of the crop's gene pool (i.e., equivalent to a gene that had evolved in a sexually compatible population of plants). The commenter does not suggest what an appropriate period of time would be, nor how this would correlate with the potential for new exposures or low probability of risk. Without additional information, it is difficult for EPA to make a finding that there is a low probability of risk, or to assess the likelihood of unreasonable adverse effects as required by FIFRA section 25(b).

iv. *What other general qualifications apply to exemptions and how do these qualifications apply to plant-incorporated protectants derived through conventional breeding from sexually compatible plants?* EPA at 40 CFR 174.21 lists general qualifications that must be met in order to qualify for an exemption from FIFRA requirements. These include qualifications relating to plant-incorporated protectants intended to be produced and used in a crop to be used as food, and to inert ingredients.

a. *Plant-incorporated protectants in a crop used as food.* As noted in Unit II., the FQPA in 1996 modified the FIFRA definition of ''unreasonable adverse effects on the environment'' by adding a criterion requiring consistency with the standard under FFDCA section 408 (Public Law 104–170 (August 3, 1996)). EPA includes at 40 CFR 174.21 a general qualification that clearly states this requirement in the context of conditions necessary for the exemption of plant-incorporated protectants.

To understand how the status of a plant-incorporated protectant under FFDCA affects the status of the plant-incorporated protectant under FIFRA, the following must be considered: first, is the plant-incorporated protectant in a crop used as food; second, are the residues of the pesticidal substance and the residues of the genetic material of that plant-incorporated protectant exempt from FFDCA section 408?

Is the plant-incorporated protectant in a crop used as food? In order to exempt a plant-incorporated protectant from regulation under FIFRA, EPA must determine that the plant-incorporated protectant poses a low probability of risk, and will not cause unreasonable adverse effects on the environment even in the absence of regulatory oversight. How a plant-incorporated protectant can meet these standards differs somewhat depending on whether or not residues of the plant-incorporated protectant are in food. As noted in Unit II., as a practical matter a plant-incorporated protectant in food cannot be exempted from FIFRA requirements unless an exemption from the FFDCA section 408 requirement of a tolerance has been issued for the residues of the plant-incorporated protectant in food.

If a plant-incorporated protectant is used in a crop used for food, unless there will be no residues in the food, the FFDCA section 408 requirements must be considered when determining whether the plant-incorporated protectant can be exempted from FIFRA requirements. To be exempted from FIFRA requirements, exemptions from the FFDCA requirement of a tolerance must exist for all of the residues of the plant-incorporated protectant. In accordance with the statutory definition of a ''pesticide chemical residue,'' EPA anticipates that in most cases the residues of a plant-incorporated protectant will consist of the pesticidal substance, the genetic material necessary to produce the pesticidal substance, any substance that might function as an inert ingredient as defined for plant-incorporated protectants (e.g., selectable marker), and the genetic material necessary for production of the inert ingredient (21 U.S.C. 321(q)).

If a plant-incorporated protectant is not used in a crop used for food (e.g., the plant-incorporated protectant is produced and used in a plant in a species used only for ornamental purposes), the FFDCA section 408 requirements do not need to be considered when determining whether the plant-incorporated protectant can be exempted from FIFRA requirements.

If the plant-incorporated protectant is used in a crop used as food, are the residues of the pesticidal substance exempt from FFDCA section 408? In a companion document published elsewhere in this issue of the **Federal Register**, EPA exempts from the requirement of a tolerance residues of the pesticidal substance portion of plant-incorporated protectants produced through conventional breeding from sexually compatible plants, and the residues of any substance used to confirm or ensure the presence of the active ingredient. The basis for this exemption is the determination that there is a reasonable certainty that no

harm will result from aggregate exposure to these residues. Thus, the answer to this question is yes for plant-incorporated protectants derived through conventional breeding from sexually compatible plants, with the limitation that the exemption does not apply when the residues are present in food at levels that are injurious or deleterious to human health. (For a detailed discussion of this limitation, see the companion document published elsewhere in this issue of the **Federal Register**.)

If the plant-incorporated protectant is used in a crop used as food, are the residues of nucleic acids that are part of a plant-incorporated protectant exempt from FFDCA section 408? The answer to this question is yes. In a companion document published elsewhere in this issue of the **Federal Register**, EPA exempts from the requirement of a tolerance residues of nucleic acids that are part of a plant-incorporated protectant because there is a reasonable certainty that no harm will result from aggregate exposure to these residues.

What is the status under FIFRA of plant-incorporated protectants derived through conventional breeding from sexually compatible plants in light of FFDCA requirements? Because of actions EPA takes in this document, and in two companion documents published elsewhere in this issue of the **Federal Register** under FFDCA section 408, plant-incorporated protectants derived through conventional breeding from plants sexually compatible with the recipient plant are exempt, whether or not they are in food, from all FIFRA requirements, except for the reporting requirements at 40 CFR 174.71.

b. *Inert ingredients*. EPA also includes at 40 CFR 174.21 a general qualification that describes how inert ingredients relate to the exemptions at 40 CFR part 174, subpart B.

With regard to how this general qualification applies to the exemption of plant-incorporated protectants derived through conventional breeding from sexually compatible plants, the preamble discussion in the 1994 **Federal Register** document (59 FR 60523) of the rationale supporting the proposal to exempt these plant-incorporated protectants extends to any substance that is derived from plants sexually compatible with the recipient plant, including substances such as a selectable marker, used to confirm or ensure the presence of the active ingredient. EPA's analysis in Units VII.D.3. and VII.D.4., applies equally to all the substances that normally characterize a population of sexually compatible plants, including inert ingredients, as long as these are derived through conventional breeding from plants sexually compatible with the recipient plant, and have never been derived from a source that is not sexually compatible with the recipient plant. An example of such an inert ingredient in sexually compatible plant populations could be tightly linked traits such as unusual leaf pigmentation always found with a pest resistance trait.

EPA includes in this final rule language at 40 CFR part 174, subpart X, to ensure that readers understand that any inert ingredient, and the genetic material necessary to produce it, that occurs naturally in a plant or is introduced through conventional breeding, is exempt when used with a plant-incorporated protectant derived through conventional breeding from a plant sexually compatible with the recipient plant. EPA believes this interpretation is a logical implication of the preamble discussion in the 1994 proposed rule (59 FR 60538).

Because the Agency recognizes that a substance with potential for adverse effects (i.e., a toxicant) could theoretically be used as a selectable marker, or inert ingredient, EPA places the same limiting condition on residues of the inert substance in food as is placed on residues of the pesticidal substance portion of the active ingredient; i.e., the residues of the substance portion of a selectable marker, or inert ingredient, do not qualify for the exemption if they are present in food from the plant at levels that are injurious or deleterious to human health.

Additional findings and conclusions supporting this exemption may be found in the companion document published elsewhere in this issue of the**Federal Register** 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.''

The regulatory text of new 40 CFR 174.485, which is entitled ''Inert ingredients from sexually compatible plant,'' can be found in the regulatory text of this document.

Under section 408(g) of the FFDCA, as amended by the Food Quality Protection Act (FQPA), any person may file an objection to any aspect of this subpart X regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA. EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(e) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(e), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days. For more details on filing objections or requesting hearings pursuant to regulations promulgated under the FFDCA, see the discussion in the companion document published elsewhere in this issue of the **Federal Register** (under ''Objections and Hearing Requests'').

v. *What were the other potential approaches to scope of exemption?* In the November 23, 1994 **Federal Register** document (59 FR 60523), EPA discussed the merits of two approaches using taxonomy, in whole (Option 2) or in part (Option 3), as a standard for describing closely related plants, and received comment on use of such a criterion. EPA also received a comment suggesting that the criterion of sequence homology be used to limit the concept of sexual compatibility.

a. *Taxonomy*. Two commenters expressed reservation about using a taxonomic standard for describing closely related plants. They pointed out that taxonomic categories, and the relationship of a given plant species to a given taxon, may be transient since taxonomic classification may change as information accrues. EPA noted in the discussion of Option 2 and Option 3 in the 1994 **Federal Register** document (59 FR 60524) that a taxonomy-based standard may be artificial: classification of plants in different taxonomic genera is not fixed and could change over time and between scientific authorities. Taxonomy reflects current observations about phenotypic, and to some extent, genotypic, differences between organisms. Currently, some plant genera are narrowly defined; for other plant genera, membership is based on broader criteria. These differences in classification criteria may lead to different probabilities between genera that new exposures may occur when genetic material from one species in a genus is introduced into another species in the genus. In recent years new tools have become available to taxonomists, allowing them to better clarify phylogenetic relationships among organisms. New information,

particularly that obtained through the use of new genetic tools, concerning organisms' properties and relationships may in the future alter current taxonomic designations. In light of these advances, EPA anticipates there may be some reorganizations among the Plantae, and that these reclassifications will better reflect the relationships among plants, and the probability of new exposures in intrageneric crosses.

The possibility that taxonomic classification may change as information accrues adds an extra layer of complexity to any regulations based on a taxonomic standard, and EPA probably would not be able to structure an exemption to accommodate for potential changes in classification. The possibility of reclassification also creates some uncertainty within the regulated community about the future status of a product.

In addition, taxonomy may be a more artificial standard than sexual compatibility as a predictor of different environmental exposures of a plant-incorporated protectant, particularly for unmanaged or semi-managed plants. Isolation, adaptation to unique environments, and low natural rates of gene flow characterize many natural populations. For these types of plants, a taxonomic standard may not be as appropriate as a standard based on sexual compatibility with regard to novel exposures to plant-incorporated protectants. At the January 21, 1994, joint meeting of the Subpanel of the SAP and the BSAC Subcommittee, the scientific advisory groups questioned whether the reasoning supporting use of a standard based on sexual compatibility supported equally well a standard based on taxonomy for semi-managed plants (e.g., trees). They indicated it probably did not for the reasons cited in this paragraph (Ref. 15).

b. *Sequence homology*. The suggested criterion of sequence homology would base relatedness on the degree of sequence homology between the source and recipient plant. Sequence homology refers to the extent that the sequence of deoxynucleotides in two pieces of genetic material are the same (Ref. 17). A deoxynucleotide is made up of a sugar, a phosphate, and one of four purine or pyrimidine bases (adenine, cytosine, guanine, thymine). The sugars and phosphates of the deoxynucleotides are covalently linked by phosphodiester bonds to form the ''backbone'' of the deoxynucleotide polymer (DNA). One base is attached to each sugar in the sugar-phosphate backbone. The information encoded in the genetic material is determined by the sequence in which the bases are attached to the sugar-phosphate backbone. The extent to which two pieces of genetic material have the same base sequence is often described in terms of percent homology, with 100% homology meaning the pieces of genetic material have an identical sequence. The Agency believes that, in general, DNA sequence homology is a less straight-forward standard for regulatory purposes than a standard such as sexual compatibility. Sexual compatibility is known in most cases, and if it is not, it is less burdensome and simpler to demonstrate than is relatedness based on DNA sequence homology. Use of homology as a criterion presents the following complex issues. First, where should homology be assessed? For example, how many genes of the source and recipient plants should be compared to determine the degree of homology? All the genes of both plants? A few genes? If only a few, which genes? Second, what degree of homology would be sufficient to indicate a high degree of relatedness? Third, under what conditions should homology be measured? Fourth, appropriate test procedures would need to be developed and validated in order to set a standard procedure for measuring homology. All of these issues would need to be resolved, and converted into regulatory text, in order to develop an exemption standard based on DNA sequence homology.

2. *How did EPA assess this category of plant-incorporated protectants?* Typically, in assessing a pesticide for environmental risk, EPA uses the information requirements generated pursuant to 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 honey bees). For most pesticides, this information is generated using animal models. To address these same questions for the plant-incorporated protectants that are the subject of this exemption, EPA was able to rely on the large and varied information base available in the public scientific literature.

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's risk evaluation relies on data generated by testing in laboratories using representative animal models to estimate risk end-points. Other information, including product analysis data and information generated by use of mathematical models, are used to develop exposure estimates. 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 is detailed in 40 CFR part 158.

The questions posed as part of the risk assessment in evaluating most pesticides (e.g., chemical pesticides) can also be posed for the plant-incorporated protectants that are exempted in today's action, and 40 CFR part 158 can be used as guidance. EPA adopted an approach for evaluating the potential risks of plant-incorporated protectants exempted by this final rule, 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 plant-incorporated protectants that are the subject of this exemption, EPA relied on a very large body of information developed through systematic scientific study that exists in the public literature (Ref. 18). This literature was developed through many decades of testing and observation. EPA thus could rely on this information and did not need to rely only on animal model testing to assess risk. EPA was also able to rely on information in the literature in evaluating the potential for exposure to the plant-incorporated protectants that are the subject of this exemption. Plant-incorporated protectants are produced within the living plant and the pesticidal substance is used *in situ* in the plant and this affects the exposure paradigm.

3. *On what basis did EPA determine that plant-incorporated protectants derived through conventional breeding from sexually compatible plants present a low probability of risk?* EPA considered several factors in determining whether plant-incorporated protectants derived through conventional breeding from sexually compatible plants could be exempted from FIFRA requirements. These include: First, the large body of knowledge that currently exists on plants in sexually compatible populations derived through conventional breeding; second, the potential for novel exposures; third, the potential for quantitative changes in the levels of substances normally found in plants in sexually compatible populations that might cause adverse effects; and, fourth outcrossing of the

ability to produce these substances to wild or weedy relatives. To support its conclusions that this category of plant-incorporated protectants present a low probability of risk, EPA also relied on the analyses laid out in the tolerance exemptions published elsewhere in companion documents in this issue of the **Federal Register**. Rather than reiterate all of these analyses here, EPA refers readers to the detailed discussions in those documents. EPA believes that the conclusions reached for plant-incorporated protectants derived through conventional breeding from sexually compatible plants also apply for other substances that might be considered part of the pesticide product (e.g., inert ingredients) for these plant-incorporated protectants.

i. *Large body of knowledge and experience exists.* In the issue paper entitled ''FIFRA: Benefit and Environmental Risk Considerations for Inherent Plant-Pesticides,'' (Ref. 18) EPA describes a large part of the information base on nontarget plants, insects, birds, mammals and other herbivores the Agency utilizes for its evaluation of the potential effects of the plant-incorporated protectants that are the subject of this exemption (Ref. 18). In addition, EPA uses the large literature on the effect on humans of consumption of food from plants in sexually compatible populations developed through conventional breeding generated from epidemiological studies, nutritional assessments, animal model testing and biochemical studies (Refs. 7, 8, 19, 20, 21, 22, 23, 24, 25, 26, and 27) to draw conclusions on the potential risk for animal non-targets, including birds and fish, which might consume food or feed containing plant-incorporated protectants that are the subject of this exemption. Just as testing in animal models can supply information that is extrapolated to conclusions on the effect of a substance on humans, so too can information and conclusions drawn in the dietary risk assessment on the effects on humans be extrapolated to predict effects on non-human mammals and other animals in an assessment of environmental risk. In addition, there is a long history of hundreds, if not thousands of years, of humans using foods containing the plant-incorporated protectants that are the subject of this exemption as feed for domesticated and other animals, including birds and fish (Ref. 28, for example). EPA relies on these experiences and the large literature generated by a century of systematic studies of the constituents of food (Refs. 7, 8, and 18) to assess the plant-incorporated protectants that are the subject of this exemption.

EPA also took into account scientific knowledge from a number of disciplines including plant genetics, plant physiology, phytopathology, entomology, biochemistry, microbial ecology, ecology and plant breeding. From these disciplines, EPA considered, for example, information on plant metabolism, the production of substances that may have a pesticidal effect, and conditions that may limit the production of such substances (Refs. 9, 17, 18, 29, and 30). The Agency also used experimental data derived from the science of phytopathology to characterize the pest resistance mechanisms in plants (Ref. 29).

ii. *Low potential for novel exposures.* Humans and the environment are currently being, and have been for long periods of time, exposed to plants containing the plant-incorporated protectants that are the subject of this exemption. Based on the knowledge base described above in Unit VII.D.2., current conditions of exposure pose a low probability of risk.

Sexually compatible plants share a common pool of genetic material, even though there may be some variability among plants in sexually compatible populations. Sexual compatibility, the ability to produce viable offspring, is only possible in nature for organisms that possess many traits in common. Traits, and the genetic material encoding them, can be passed through a sexually compatible plant population by mating, and the mixing of genetic material that occurs through mating tends to a situation where the members of a sexually compatible population have similar traits and similar genetic material. Thus, movement through conventional breeding of genetic material encoding pesticidal substances between plants in a sexually compatible population is unlikely to result in exposure of organisms that associate with a plant in that population to plant-incorporated protectants that they, and their ancestors, had not been exposed to previously. If a population of plants normally possesses a pesticidal substance, organisms that come into contact with some plants in that population have likely been exposed to that substance in the past, perhaps over long periods of time. These past exposures, particularly if they occur over long periods of time, may lead to a degree of adaptation, or tolerance, in the population of organisms exposed to the pesticidal substance (Ref. 9). The potential for novel, or significantly different environmental exposures to occur in such a situation, would be low.

Further, the potential for exposure to plant-incorporated protectants is in general lower than for other types of pesticides, because plant-incorporated protectants are produced within the living plant and used *in situ* in the plant. Most other pesticides must be applied to the plant, or near the plant. Because a plant-incorporated protectant is produced and used within the plant, physiological constraints limit the amount of pesticidal substance produced by the plant. Because the plant-incorporated protectant is within the plant, the routes by which other organisms may be exposed to the plant-incorporated protectant may be more limited, e.g., dietary exposure is likely to be the predominant route of exposure. Because plant-incorporated protectants are produced and used in the living plant, actual physical contact with the plant or plant parts will, in general, be necessary for exposure to occur. In addition, the plant-incorporated protectants exempted by this final rule are part of the metabolic cycles of plants. They, thus, are biotic and are subject to the processes of biodegradation and decay that all biotic materials undergo (Ref. 31). Biotic materials are broken down to constituent parts through the enzymatic processes of living organisms, and these constituent parts used as building blocks to make other biotic substances. Furthermore, the plant-incorporated protectants that are exempted in this action are biodegradable to their constituent elements through catabolism by living organisms. Because of their biodegradable nature, these plant-incorporated protectants do not bioaccumulate (bioaccumulation occurs when a substance is taken into the body through processes such as eating, and as the body is unable to either break the substance down or eliminate it, the substance accumulates in the tissues) or biomagnify (biomagnification occurs when a substance bioaccumulates in the bodies of organisms lower in the food chain, and as predators higher in the food chain consume organisms lower in the food chain, more and more of the substance accumulates in the bodies of organisms higher in the food chain) in the tissues of living organisms as do substances, such as dioxin (Ref. 32). Because of these characteristics, the potential for new exposures to occur, beyond direct physical exposures to the plant or plant parts, is limited for plant-incorporated protectants derived through conventional breeding from sexually compatible plants.

EPA received a comment raising the concern that ''wild-type or

conventionally bred plants in new environments attract, repel or otherwise influence biota surrounding them.'' In response, EPA would first point out that as described in Unit VII.B.5., a key statutory element in the FIFRA definition of pesticide is whether a human ''intends'' that a substance or mixture of substances be used for destroying, preventing, repelling or mitigating a pest. A plant introduced into the United States with reference only to its ornamental beauty or its food value, without regard to ability to resist pests, does not contain substance(s) meeting the FIFRA section 2(u) definition of pesticide until a human intends the substance(s) be used for preventing, destroying, repelling or mitigating a pest. Substances within a plant introduced into the United States with pesticidal claims are pesticides within the FIFRA section 2(u) definition. However, as pointed out by the commenter, these substances would be exempt from FIFRA requirements if derived through conventional breeding from sexually compatible plants even though they present a potential for novel environmental exposure. EPA believes this is appropriate. When EPA proposed to exempt plant-incorporated protectants derived from sexually compatible plants from FIFRA requirements, EPA recognized that most crop plants, including all major crop plants, were not native to the United States. The risk assessment the Agency performed and its analysis of risks versus benefits as prescribed by FIFRA, led it to propose the exemption based on a determination that the benefits of use of agricultural crops already in the United States outweigh the low probability of risk. The Agency also anticipated that the probability that nonindigenous plants representing wide-spread exposure being commercially introduced into the United States with pesticidal claims in the future was low (Ref. 7). EPA also considered that the adverse effects reporting requirement it was placing on the exemption would serve to alert the Agency should any environmental or human health risk be identified with such plants. In addition, EPA considered whether new dietary exposures could occur with such plants. EPA concluded that for any such plant introduced into the United States for food use, there will likely be in the country of origin, a history of experience with the dietary use of the plant or parts of the plant, even if a similar history does not exist in the United States at the time of the introduction. In performing its analysis of dietary risk, EPA found no basis for assuming that the dietary effects of any plant-incorporated protectant residues in such a food from such a plant would differ for the United States population from that of the source country. Moreover, EPA believes that the limitation in the tolerance exemption for residues of the pesticidal substance portion of plant-incorporated protectants derived through conventional breeding from plants sexually compatible with the recipient plant will allow EPA and FDA to act expeditiously should any substances meeting the FIFRA section 2 definition of pesticide be identified as problematic.

iii. *Low potential for significant increases in levels of plant-incorporated protectants.* EPA has evaluated whether there are likely to be quantitative changes in levels of plant-incorporated protectants derived through conventional breeding from sexually compatible plants, such that adverse effects on the environment might occur. EPA has determined that the probability of such an event is low because the highest levels of pesticidal substances likely to be attained with plant-incorporated protectants in this group are not likely to result overall in significantly different environmental exposure levels. This analysis was presented in an EPA issue paper, entitled: ''Benefit and Environmental Risk Considerations for Inherent Plant-Pesticides'' (Ref. 18) located in the record for this rule as described in Unit VIII. A summary of the analysis is presented here.

EPA first considered whether an increase in the levels of substances, including plant-incorporated protectants, that plants normally produce is likely to exceed the ranges normally found within and between plant varieties and uncultivated plants. The level of production of such substances normally varies among sexually compatible plants because of differences in potential to express a substance and environmental conditions. Indeed, variation is seen even among plants in the same variety because of differences such as weather and soil condition. For example, one report (Ref. 7) has shown an 8.3-fold variation in the amount of ascorbic acid in turnip greens depending on the degree of exposure to light. Such variation could also characterize natural variation in the levels of a plant-incorporated protectant and variation in exposure for organisms that associate with the plant. Nontarget organisms, such as birds and insect pollinators, that associate with plants have been, and are currently being exposed to the range of levels of plant-incorporated protectants being expressed by plants within sexually compatible populations. This exemption will not affect these exposure patterns.

EPA also considered the extent to which any substance can be increased in highly managed plants without unwanted effects on other, desirable characteristics of the plant such as yield or palatability of fruit. In general, breeders balance all of these characteristics in developing marketable plant varieties. Plants have, as do all organisms, only a limited capacity to express a particular trait without a drain on energy reserves. Greatly increased levels of a plant-incorporated protectant would, in general, only be accomplished at the expense of the expression of other, agriculturally desirable traits (Ref. 18).

EPA anticipates that for the majority of agricultural plants, levels of expression of substances such as plant-incorporated protectants will continue to fall within currently observed ranges of expression; EPA does not anticipate that variations in the level of a plant-incorporated protectant that is normally a component of a plant and derived through conventional breeding from plants sexually compatible with the recipient plant would lead to a significantly different spectrum of exposure to a plant-incorporated protectant. Moreover, EPA believes that the history of familiarity with agricultural plants in sexually compatible populations, and thus with the likely progeny of genetic exchanges between plants in such populations, and the procedures currently employed in plant breeding to screen out undesirable traits also support this conclusion.

Comments on quantitative changes and on the potential for plants consumed *in toto* or in part as food to produce injurious or deleterious effects have, however, caused EPA to reconsider its approach under FFDCA to pesticidal substances derived through conventional breeding from sexually compatible plants. To address concerns raised in comment on the possibility that certain substances normally present in plants in sexually compatible populations may in rare circumstances be present in food at levels that are hazardous, EPA places a condition on the exemption under FFDCA section 408 for pesticidal substances derived through conventional breeding from sexually compatible plants. Eligibility for exemption is based on the condition that the residues of the pesticidal substance not be present in food from the plant at levels that are injurious or

deleterious to human health. If the residues of the plant-incorporated protectant do not meet this criterion, they are not exempt from the requirement of a tolerance. Because the residues would not qualify for the exemption and no tolerance would have been established, any food containing such residues would be ''adulterated'' pursuant to section 402(a)(2)(A) of the FFDCA and subject to seizure (21 U.S.C. 342 (a)(2)(A)). As noted in Unit II., the status of a plant-incorporated protectant under FFDCA can affect its status under FIFRA.

EPA also considered issues of variation in levels of plant-incorporated protectants and exposure of nontarget organisms to such plant-incorporated protectants for plants in semi-managed systems (e.g., trees) (Ref. 18). EPA anticipates that for such plants, levels of expression of substances such as plant-incorporated protectants will continue to fall within currently observed ranges of expression. EPA does not anticipate that variations in the level of a plant-incorporated protectant in these plants would lead to a significantly different spectrum of exposure to a plant-incorporated protectant. It is not anticipated that the levels of plant-incorporated protectants in these plants would significantly exceed existing expression ranges of their free-living relatives (Ref. 18).

One commenter worried that because levels of substances in plants vary in response to environmental conditions, the legal status of a plant-incorporated protectant could change from exempt to non-exempt as the levels of pesticidal substances fluctuate. While it is possible, particularly in light of the condition placed on the exemption from the requirement of tolerance, that the legal status of a plant-incorporated protectant could change from exempt to non-exempt, EPA anticipates this will occur only very rarely, if at all. In its assessment, EPA considered the probability of variations in levels of plant-incorporated protectants derived through conventional breeding from sexually compatible plants presenting risk. EPA concluded that although variations will occur in response to environmental conditions, in the range of levels likely to occur they pose a low probability of risk from quantitatively different exposures. EPA's conclusion that it is unlikely that variation due to environmental conditions, or to breeding decisions, would result in risk from quantitatively different exposures is reflected in the Agency's reliance on the post marketing monitoring afforded by the adverse effects reporting requirement at 40 CFR 174.71.

iv. *Low potential for weediness from outcrossing from plants derived through conventional breeding to wild relatives.* 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 plant-incorporated protectants. Because plant-incorporated protectants are produced and used in the living plant, the possibility that the ability to produce a plant-incorporated protectant may be transferred by outcrossing and hybridization from the crop plant to a cultivated, wild or weedy relative was considered for the plant-incorporated protectants exempted in this action. A large volume of information is available in the public literature (Ref. 33) on this possibility for plant-incorporated protectants derived through conventional breeding from sexually compatible plants. EPA's issue paper entitled ''Risk Considerations for Outcrossing and Hybridization'' describes in part the information base used to address this aspect of the assessment (Ref. 33).

One of the considerations evaluated for this exemption was whether a capacity to express higher levels of pesticidal substances could be transmitted to wild relatives through outcrossing of the genetic material necessary for the production of the pesticidal substance. A second and more important consideration is whether such an outcrossing event, could in turn, increase weediness of the wild relative. EPA believes that the potential for weediness to increase in wild relatives through the transfer of the genetic material for the pesticidal substance from a crop plant is low for the following reasons.

First, there are several factors which govern whether gene flow occurs between crops and their wild relatives (Ref. 34). Genetic barriers can prevent hybrids from forming, render them sterile, or reduce the fertility of hybrids, and, thus, restrict their contribution to subsequent generations. The strength of genetic barriers is correlated to degree of evolutionary relatedness between the crop and wild relatives (Ref. 34). Space is an effective barrier to hybridization. The wild relatives of corn with which it can hybridize, are restricted to Mexico and Central America. There is no danger of hybridization in other regions (Ref. 34). Time of flowering can prevent hybridization when there is no overlap in the time of flowering of cultivated and wild forms (Ref. 34). The breeding system of the crop plays an important role. For some species (e.g., peanut), the flowers do not ordinarily open, and self-pollination may be very near 100% (Ref. 34). The ploidy level may differ between a crop and its relatives, and differences in ploidy levels can severely reduce the likelihood that the cultivated plant and wild relative will form fertile hybrids (Ref. 34). Some varieties of certain crop species, such as banana, are sterile, and thus are incapable of hybridizing not only with members of other species, but also of their own species (Ref. 34). For some crops in the United States, the probability of gene transfer and hybridization with the wild relative is zero, while for other crops, despite the variety of potential barriers to and selection against hybridization, it is possible.

Second, in general, wild members of sexually compatible populations tend to already possess higher levels of resistance to pests and disease than do the cultivated members of those populations (Ref. 18). Wild members of sexually compatible plant populations also tend to express a greater range of levels of inherent plant defense compounds than do cultivated plants, including production of higher levels of substances that could potentially be used as plant-incorporated protectants (Ref. 18). Indeed, during the past 100 years, it has been common practice to cross crop plants with sexually compatible wild relatives, since these wild relatives usually have higher levels of resistance to a pest, in order to develop crop varieties with improved resistance to the pest. For example, wild species of tomatoes have been used, in conventional plant breeding, as a source of increased resistance to economically important diseases in tomato (Ref. 7).

EPA anticipates that for the majority of agricultural and semi-managed plants, levels of expression of substances such as plant-incorporated protectants, within plants in sexually compatible populations, will continue to fall within currently observed ranges of expression. EPA does not anticipate that variations in the levels of substances such as plant-incorporated protectants, that are normally components of a plant would lead to a significantly different range of expression as a result of this exemption (Ref. 18). Thus, even should a crop plant containing a plant-incorporated protectant in this exempt category hybridize with a wild relative, it is unlikely that the range of expression of the plant-incorporated protectant by the wild relative will be substantially increased by acquisition of the trait from the crop plant.

4. *On what basis did EPA determine that these plant-incorporated protectants are not likely to present*

unreasonable adverse effects to the environment even in the absence of oversight? As explained in Unit II., a pesticide chemical meets the standard for a FIFRA 25(b) exemption if the risks resulting from use of that pesticide are consistent with the FFDCA section 408 exemption standard, and the potential benefits of use outweigh any human health or environmental risks even in the absence of regulatory oversight. EPA considered several factors in determining whether the exempted plant-incorporated protectants are not likely to cause an unreasonable adverse effects to the environment. These include consideration of the potential for dietary, both non-occupational and occupational human health risks, and environmental risks. Also considered was whether the language of the exemption clearly describes for the regulated community what plant-incorporated protectants are exempt; how the scope of the exemption under FIFRA relates to a companion exemption from the FFDCA requirement of a tolerance for residues of these plant-incorporated protectants; and general benefits to society, growers, consumers and the environment.

Some of these considerations were analyzed in detail in the tolerance exemptions published elsewhere in companion documents in this issue of the **Federal Register**. Rather than reiterate the analyses here, the Agency has, in this section, limited its discussion of the human health risks addressed in great detail in those documents to the remaining risks for which the probability is so low that, notwithstanding their existance, the residues meet the section 408(c) standard. The standard for granting an exemption under section 408(c) requires a ''reasonable certainty of no harm,'' not absolute certainty. EPA can make the safety finding required under FFDCA section 408(c) based on an extremely low probability or risks; a demonstration of ''no risk'' is not required.

i. *Dietary risk considerations*. EPA has determined that there is a reasonable certainty that no harm will result from aggregate exposure to residues of the plant-incorporated protectants that are the subject of this exemption. For a full explanation of the factual bases for this determination, readers are referred to EPA's assessment of human dietary risks in the tolerance exemptions published elsewhere in companion documents in this **Federal Register**, and to related documents in the record for the rule as described at Unit VIII.

In addition, the Agency evaluated the remaining dietary risks that pose a negligible probability of causing adverse effects. As explained throughout this preamble, and in associated rules, EPA believes that the likelihood of dietary risks associated with the residues of plant- incorporated protectants that are the subject of this exemption are extremely low. However, it is possible that, notwithstanding the best efforts of plant breeders, a toxicant could enter the food supply at levels that could cause adverse effects. Because of the conditions of the exemption, such food would no longer qualify for the exemption, and would be subject to seizure. Thus, the extent of the harm is anticipated to be extremely low.

ii. *Occupational and non-occupational risk to humans*. Plant-incorporated protectants are likely to present a limited exposure to humans. In most cases, the predominant, if not the only, exposure route will be dietary. Significant respiratory and dermal exposures are unlikely because the substances are in the plant tissue and thus are found either within the plant or in close proximity to the plant. Although a potential for non-dietary exposure (e.g., dermal and inhalation) in occupational settings may exist, EPA expects such exposure to be negligible and thus human health risks to be negligible.

a. *Dermal exposure*. Plant-incorporated protectants derived through conventional breeding from sexually compatible plants may in some cases be present in sap or other exudates from the plant or the produce 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. Farmers and food handlers (e.g., individuals harvesting produce by hand, preparing food for sale, or stocking produce bins in grocery stores) or floral workers, are those most likely to experience dermal contact with the substances on an occupational basis. Although contact dermatitis is fairly common in such workers (Refs. 35 and 36), these dermal reactions are generally mild, of a self-limiting nature or self-diagnosed, and treated.

Most of the substances that could be the subject of this exemption are unlikely to pass through the skin to affect other organ systems (Refs. 36 and 37). For those substances which possess to some degree properties that allow some penetration of the skin, the potential amounts passing through the upper layer of the skin (epidermis) are negligible or the substances do not present adverse effects (Ref. 36).

A group of substances that might be plant-incorporated protectants, if humans intend to use them as pesticides, with the ability to present an effect on dermal exposure in the occupational setting beyond a mild contact dermatitis are the psoralens. These substances occur naturally in a wide range of plants but occur in the highest concentrations in celery, dill and parsley (Refs. 8 and 36). Psoralens can be phototoxic to the skin in conjunction with sunlight (UV light). Due to their relative solubility in oils, psoralens can penetrate into the skin cells, where they intercalate into the genetic material of the skin cell (Ref. 8). Subsequent exposure to sunlight (UV light) causes the genetic material to ''cross link'', affecting the ability of the cell to further process its genetic material. This may result in skin blisters and rashes. This UV-dependent phototoxicity has also been implicated in mutations that may lead to skin cancer (Ref. 8). In spite of the potential for this type of adverse effect with the psoralens, there are few reported incidents of this type of problem for substances derived through conventional breeding from sexually compatible plants. There is one reported incident in the 1980's where a celery variety with high levels of psoralen caused rashes and dermatitis in produce handlers (Ref. 7). The problem was identified and the variety removed from the market.

b. *Inhalation exposure*. Plant-incorporated protectants derived through conventional breeding from sexually compatible plants may in some cases be present in pollen and some individuals (e.g., those working on farms in nurseries or other plant-growing areas) may be exposed, through inhalation, to wind-blown pollen. When present in pollen, the pesticidal substance is likely to be integrated into the tissue of the pollen grain. Pollen grains are solid, insoluble particles of sufficiently large diameter that they are filtered out in the nasopharynx or in the upper respiratory tract (Refs. 36 and 38). This exemption will not change current exposures nor affect strategies for dealing with plant-incorporated protectants that are the subject of the exemption (Refs. 36 and 38).

iii. *Environmental considerations*. EPA examined, in Unit VII.D.3., the potential for environmental effects from the plant-incorporated protectants that are exempted by this action. The Agency has determined on the basis of its analysis that the probability of novel exposures to nontarget organisms and to the surrounding ecosystems are low. EPA's analyses indicate that the risks of outcrossing with wild relatives are also anticipated to be low. Similarly, EPA's

analyses indicate that the risks of groundwater, or surface water, contamination from these products are extremely low. EPA has thus concluded that potential risks of environmental effects are not significant.

iv. *Exemption criteria provide high degree of regulatory clarity.* EPA believes that using sexual compatibility coupled with the process by which the plant-incorporated protectant is introduced into a plant as a standard affords the most clear description of whether a plant-incorporated protectant is exempt. Most plants have some form of sexual reproduction characterized by the formation of gametes from haploid germ cells, although some do not (Ref. 9). The definition of conventional breeding at 40 CFR 174.3 provides for this latter category of plants, which reproduce vegetatively. Plants reproduce either by sexual processes or vegetative reproduction, and the limitations posed by these natural barriers limits the transfer of genetic material to plants within a sexually compatible population. These barriers can also be effectively used to establish scope within regulations for plants.

In most cases, whether two plants are sexually compatible is known; thus, testing to determine whether the plants are sexually compatible is not likely to be necessary. If, in some cases, it is not known whether two plants are sexually compatible, the means of determining sexual compatibility is straightforward and simple. Sexual compatibility is empirically demonstrable. EPA believes that a standard based on sexual compatibility provides a high level of regulatory clarity and great ease of implementation. This standard allows the public, industry, and EPA to easily and readily identify those plant-incorporated protectants that are exempt.

v. *Exemption criteria create similar scopes under FIFRA and FFDCA section 408.* When EPA proposed its exemptions in 1994, one of its goals was to create as similar a scope of exemption under FIFRA and the section of FFDCA dealing with pesticides as possible, given the differences in mandate and structure of the two statutes. EPA believed that because it utilized the two authorities in concert to regulate pesticides, similar exemptions under the two statutes would be desirable. Such an approach would be simpler for the regulated community to understand and for EPA to administer.

In considering dietary risk under FFDCA section 408, EPA concluded that a standard based on sexual compatibility exempts those plant-incorporated protectants for which there is a reasonable certainty that no harm will result from aggregate exposure. EPA, in a companion document published elsewhere in this issue of the **Federal Register**, exempts from the FFDCA section 408 requirement of a tolerance, residues of pesticidal substances derived through conventional breeding from sexually compatible plants. The information supporting that exemption was generated on food from plants in sexually compatible populations developed through conventional breeding.

vi. *No undue burden.* The standard provided by criteria based on sexual compatibility creates a similar exemption under FFDCA and FIFRA, while at the same time implementing the standard with a high degree of regulatory clarity. Implementing a standard with a high degree of regulatory clarity that also creates similar exemptions under FFDCA and FIFRA results in less burden on producers. In addition, EPA believes that implementation of the exemption described in this document, and the exemptions under FFDCA section 408 published elsewhere in companion documents in this issue of the **Federal Register**, and the clarification that plants used as biological control agents are exempt from FIFRA requirements, minimize the burden of producers/developers while appropriately addressing risk.

One comment questioned the cost of EPA's proposed exemptions (59 FR 60519), appearing to believe that research scientists and industry would have to notify and consult with EPA in order to qualify for exemption. This final rule does not require producers to notify or consult with EPA, or present data to the Agency in order to qualify for exemption. The producer would determine whether a particular plant-incorporated protectant meets the exemption criteria. EPA expects that a producer will not have to create additional information specifically to determine if a product is exempt, because producers will already have such information from the ordinary course of product development. There is no requirement to notify EPA associated with the exemption, and no costs can be ascribed to such a notification process.

Some comments offered general observations that costs would curb the development of crop varieties. EPA believes that the clarification that it will not regulate plants per se, and the exemptions it is publishing in this document and in companion documents in this issue of the **Federal Register**, limit EPA's effect on plant breeding and allow most aspects of plant breeding to be pursued without EPA regulation.

Some comments suggested that costs would inhibit the development of alternatives to chemical pesticides. EPA has been, and continues to be, committed to the development of safer pesticides, many of which are biological pesticides, as possible alternatives to more toxic pesticides. The Agency believes the actions it takes with regard to plant-incorporated protectants encourage public confidence in the safety of plants and foods from plants, developed using traditional and modern techniques of biotechnology. The Agency believes that consumer acceptance is key to the success of agricultural products, and that consumer acceptance is strongly influenced by confidence that regulatory agencies have ensured the public safety.

vii. *Benefits.* The benefits to society associated with exemption from FIFRA requirements of this category of plant-incorporated protectants include general benefits to society from the practices of horticulture and of agriculture in producing the food supply and other plant based products (e.g., fiber, lumber), and economic benefits to growers, and the environment.

a. *General benefits to society.* Agriculture based on conventional breeding allows much of the current world population of 6 billion humans to feed itself. Development of higher yielding varieties through conventional breeding in sexually compatible crop plant populations has been an important means of feeding a growing human population (Refs. 39 and 40). For example, it has been estimated that the development of new varieties of plants in sexually compatible populations through conventional breeding accounts for about 80% of the increase in corn yields from 1930 to 1980 and more than half of the increase in soybean yields since 1920 (Refs. 41, 42, and 43). Similarly, genetic improvements of plants in sexually compatible populations through conventional breeding have been estimated to account for half the increase in wheat yields from 1954 to 1979, almost two-fifths of the increase in sorghum yields from 1950 to 1980 (Refs. 44, 45, and 46). This exemption of plant-incorporated protectants derived through conventional breeding from sexually compatible plants will allow the type of genetic modifications leading to these types of yield gains to continue with very minimal regulatory requirements.

b. *Growers.* Growers who use plant-incorporated protectants derived through conventional breeding from sexually compatible plants should be

able to maintain or increase their productivity. Use of these plant-incorporated protectants could translate into lower grower costs because growers will use fewer inputs. Growers should be able to reduce the amount and type of chemical pesticides applied to a crop. Chemical costs, energy costs (e.g., use of tractor) and labor expenditures will be lower if the number of chemical pesticide applications decrease (Refs. 47, 48, and 49). This category of plant-incorporated protectants may also offer economic benefits to growers in circumstances where traditional pesticides may not be as effective. For example, because plant-incorporated protectants are produced and used in plants, they may be more useful for combating pests that act systemically (e.g., stalk borers) than are some traditional pesticides sprayed on the plant.

c. *Consumers*. Lower food prices for consumers are anticipated through use of plant-incorporated protectants derived through conventional breeding from sexually compatible plants, because the use of these plant-incorporated protectants may contribute to, or help maintain, yield increases. If yields increase, the supply of food should also increase. Consumer purchasing power could potentially increase with the decrease in food prices.

d. *Environment*. Environmental benefits associated with the use of plant-incorporated protectants derived through conventional breeding from sexually compatible plants include reduction in the use of chemical pesticides. These chemical pesticides may not be environmentally benign (Refs. 47, 48, and 49). Assuming that growers reduce the number and type of chemical pesticide applications, field workers would have reduced exposure. Other problems associated with chemical pesticide use such as spray drift to other crops or plants, exposure of nontarget species, groundwater contamination and spills could also be reduced.

In addition, breeding programs that develop varieties with, for example, increased yield, better resistance to pests, and better nutritional quality, could be part of an approach to agriculture that would decrease some of the impacts of agriculture on the environment while continuing to supply food to the growing human population. For example, breeding programs that increase crop yields could reduce some of the future impacts of agriculture by decreasing the amount of additional land that would have to be brought into agricultural production to feed the growing human population. The exemption described in this document would allow breeding activities among plants in sexually compatible populations through conventional breeding to continue while imposing minimal burden.

Finally, by exempting those plant-incorporated protectants unlikely to result in novel exposures, EPA is concentrating its regulatory efforts on those plant-incorporated protectants about which less certainty exists with regard to the risk that would result from the use of the plant-incorporated protectant. EPA would, for example, focus its efforts on plant-incorporated protectants such as the toxin from a spider. This toxin is targeted for the insect prey of the spider mite. Plants are not known to produce this toxin in nature or in cultivation. If this toxin were to enter the gene pool of a plant, organisms that associate with the plant and that had never previously been exposed to the toxin could now be exposed. Prior to the introduction of the toxin into these plants, only the insect prey of the spider would potentially be exposed to the toxin. If plants could now express the toxin, a different or larger group of organisms could be exposed to it, possibly resulting in adverse effects to these organisms. For example, if the toxin is found in pollen, pollinators could be exposed to the toxin. By concentrating its regulatory efforts in this way, EPA more efficiently uses its own resources.

viii. *Reporting of adverse effects for exempted plant-incorporated protectants*. EPA has decided to adopt its proposed reporting requirement for otherwise exempt plant-incorporated protectants. Under 40 CFR 174.71, anyone who produced an otherwise exempt plant-incorporated protectant will be required to report any adverse effects associated with the testing or use of the exempted plant-incorporated protectant. Failure to comply with 40 CFR 174.71 would be an unlawful act under FIFRA section 12(a) and could result in monetary penalties pursuant to FIFRA section 14.

As discussed throughout this preamble, EPA's analysis of the potential risks has led it to conclude that the plant-incorporated protectants that are the subject of this exemption present a low probability of risk. But the Agency cannot rule out completely the possibility of adverse effects to human health or the environment from the testing and use of this large category of exempted plant-incorporated protectants. The Agency cannot foresee all potential adverse effects to human health and the environment that may potentially arise for testing and use of specific plant-incorporated protectants. This is compounded by the fact that the exemption is broad, covering literally thousands of potential substances, some of which have the potential to be toxic (Ref. 8, for example). The reporting requirement is meant to address such unforeseeable events resulting from the use of these pesticides.

After weighing the remaining low probability of potential risks against the potential benefits of the plant-incorporated protectants within this category, EPA determined that the risks outweighed the benefits in the complete absence of regulatory oversight. Even though the potential benefits are very high, and the likelihood of risks are estimated to be low, the nature of the potential hazard, a toxicant(s) in the food supply, is extremely significant. Moreover, these products present issues not seen with traditional pesticides: the potential for spread of the plant's genetic material. Because plants can reproduce sexually and/or asexually, the ability to produce the plant-incorporated protectant could spread through the agro- or natural ecosystems, particularly if wild relatives acquire the ability to produce the plant-incorporated protectant through successful hybridization. In addition, the extremely large category of substances that will be exempt itself adds some degree of uncertainty to the Agency's finding. EPA continues to believe that such risks are likely to be extremely rare. However, these considerations would outweigh even the benefits of the plant-incorporated protectants that are the subject of this exemption in the absence of regulatory oversight.

However, as discussed in Unit VII.D.5., EPA does not believe that these risks justify requiring these products to be subject to the full degree of regulatory oversight under FIFRA. Rather, taking into account the very low probability of the risks, EPA believes that the post-market requirement to report adverse effects, when taken with the condition of the FFDCA exemption limiting the level of toxicants, represents a sufficient degree of oversight to allow the Agency to determine that the benefits outweigh the risks. The reporting requirement at 40 CFR 174.71 is a means of ensuring that EPA and FDA can address any potential hazard, and that the Agency's data base with respect to such products is as complete as possible. The costs of reporting are low for the regulated community, being calculated at $669.00 per notification, with EPA anticipating three adverse effects reports in 20 years,

but, as noted in the preceding paragraph, among other benefits, it will provide a mechanism that will allow EPA and FDA to react quickly to address the hazard, in the unlikely event it should arise. (See the Economic Assessment for this rule (Ref. 50)). Therefore, to ensure that there will be no unreasonable adverse effects on the environment from the plant-incorporated protectants that are the subject of this exemption, EPA is including in this final rule the reporting requirement codified at 40 CFR 174.71.

a. *Comments on the reporting requirement*. The majority of comments supported the Agency's proposal. Two of these comments noted that traditionally bred plants are monitored, both formally and informally, for desirable properties, as well as for pests and disease, and suggested that the Agency include a ''sunset clause'' in the requirement.

One comment disagreed with the adverse effects reporting requirement and pointed out that the language of the proposed rule has the potential of bringing in numerous reports of effects that are not due to the plant-incorporated protectant.

EPA carefully examined the comments it received on the proposed adverse effects reporting requirement, including comments received from other Federal agencies during the review process for this rule. In establishing this reporting requirement EPA took into account the need to target the requirement so that to the extent possible the Agency would not receive numerous reports of effects that are not due to the plant-incorporated protectant. On the other hand, guidance on what to report that is too specific would be counterproductive given that the purpose of the requirement is to be able to monitor for unforeseen events. EPA balanced all of these considerations in developing its final adverse effects reporting requirement at 40 CFR 174.71.

EPA will not adopt a ''sunset clause'' for this requirement, i.e., a clause that would designate a period of time after which information regarding adverse effects would no longer need to be reported to EPA. EPA appreciates that plant breeders monitor for properties such as yield, nutrients and resistance to pests. However, EPA does not have adequate information on which to base such a clause. The commenters do not define the parameters of the suggested ''sunset clause.'' In addition, records would probably have to be kept to know when reports would no longer be required for a particular plant-incorporated protectant, adding an additional level of complexity to the requirement. Finally, EPA believes that adverse effects reporting for otherwise exempt plant-incorporated protectants should be the responsibility of persons who produce plant-incorporated protectants for sale or distribution. Plant breeders are not necessarily involved in sale and distribution activities, and thus their access to information that an adverse effect may have occurred may be limited.

With regard to the concern expressed with respect to over-reporting, EPA recognizes that the proposed regulatory text (59 FR 60535) could have led to the submission of information that was not relevant to EPA's primary concern of adverse effects caused by the plant-incorporated protectant. In addition, the proposed requirement would have applied to some persons who would not necessarily be in a position to know if adverse effects had occurred. Therefore, EPA has revised the language of the regulatory text at 40 CFR 174.71 of the final rule to clarify that the Agency's intention is to provide a mechanism for reporting information on adverse effects related to a plant-incorporated protectant in a plant, and that only persons who ''produce'' plant-incorporated protectants for sale and distribution are responsible for submitting information to EPA. This requirement applies to the person who manufactures, for sale or distribution, a plant-incorporated protectant. It does not apply, for example, to researchers performing field experiments, nor to breeders making crosses among plant varieties with the goal of developing new plant varieties, nor to a person who only sells propagative materials (e.g., seed) to farmers without producing the propagative materials themselves.

During interagency discussion on this final rule, the question was posed of whether the commonly observed phenomenon of emergence of resistance in a pest population to one variety of plant, which necessitates the replacement of that one variety by another variety of the same crop plant, would be considered reportable by EPA under 40 CFR 174.71. EPA recognizes that this phenomenon occurs continually in agriculture and is one of the primary reasons that conventional plant breeding programs were instituted and continue to be needed by farmers. Plant breeders must continually develop plant varieties to counter the evolution in pest populations of the ability to be able to successfully attack a previously resistant variety. EPA, when it evaluated plants in sexually compatible populations for potential exemption from the requirements of FIFRA, took this phenomenon into account. Although in some instances, e.g., for Bt plant-incorporated protectants, the evolution of resistance to a pesticide in pest populations is of concern (Ref. 51), based on the history of plant breeding, adaptation between pest and plants in populations of sexually compatible plants derived through conventional breeding should not trigger adverse effects reporting under § 174.71.

b. *Guidance on adverse effects reporting*. To further address the comment that this requirement may lead to over-reporting, EPA has clarified both the procedures for reporting and the types of incidents that must be reported to meet the reporting requirement at 40 CFR 174.71. The text at 40 CFR 174.71 describes the conditions under which reporting should occur, the information which, if available, should be provided in the report, and where the reports should be directed at the EPA. In addition, EPA intends to develop specific guidance to provide further assistance to avoid confusion and unnecessary reporting. For example, the guidance would reiterate that this final rule does not require researchers to notify or consult with EPA, unless they are selling or distributing the plant-incorporated protectant to the public. As indicated previously, producers who sell or distribute an otherwise exempt plant-incorporated protectant must only notify EPA if they have information on actual adverse effects. Furthermore, this final rule does not require anyone, including researchers, to maintain any records.

EPA, in developing the adverse effects reporting requirement at 40 CFR 174.71 for otherwise exempt plant-incorporated protectants, was cognizant that in rare circumstances unanticipated effects may occur with a plant-incorporated protectant. For example, although the Agency judges it highly unlikely, it is possible that a celery variety expressing, for pesticidal purposes, high enough levels of psoralen, to cause dermatitis in humans, could arrive on the market. A celery variety expressing such levels emerged from the varietal development programs once in the past 50 years (Ref. 7). It is to enable the Federal government to address quickly circumstances of this magnitude that EPA implements the reporting requirement at § 174.71 for otherwise exempt plant-incorporated protectants.

If the producer believes the effect is due to consumption of a food but is unsure whether the effect was due to a plant-incorporated protectant, the incident must still be reported to EPA. While reports on human health would be made to EPA, EPA will share such reports with FDA, and EPA and FDA

will make a determination of whether any action is necessary to protect the public health, and if so, what constitutes appropriate action.

c. *Relationship of 40 CFR 174.71 reporting requirement to other reporting requirements*. The reporting requirements imposed upon registrants under FIFRA section 6(a)(2) for registered pesticides (including registered plant-incorporated protectants), and under 40 CFR 152.50(f)(3) for applicants for a registration are not affected by this provision. Nor would either 6(a)(2) or 40 CFR 152.50(f)(3) apply to those who would be subject to 40 CFR 174.71.

5. *Statutory finding*. EPA concludes that plant-incorporated protectants, derived through conventional breeding from plants sexually compatible with the recipient plant, as described at 40 CFR 174.25, warrant exemption under FIFRA section 25(b) because these substances are of a character that is unnecessary to be subject to FIFRA in order to carry out the purposes of the Act. EPA makes this finding with respect to both active and inert ingredients derived through conventional breeding from sexually compatible plants.

As discussed above, EPA has determined that plant incorporated protectants derived through conventional breeding from sexually compatible plants, pose a low probability of risk to humans and the environment. As explained in this preamble, and in the tolerance exemptions for the residues of such plant-incorporated protectants published elsewhere in this issue of the **Federal Register**, EPA has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the residues of such products, including all anticipated dietary residues and all other exposures for which there is reliable information. EPA has also determined that these pesticide products pose a low probability of non-dietary risks to humans and the environment. The Agency bases these conclusions on information from the fields of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry, and plant breeding, supplemented by the hundreds, if not thousands, of years of experience growing and consuming plants that contain the substances that are the subject of this exemption, and by Agency knowledge of horticultural and agricultural practices.

EPA has also determined that the use of plant-incorporated protectants is not likely to cause unreasonable adverse effects on the environment in the absence of regulatory oversight other than the adverse effects reporting requirement at 40 CFR 174.71.

The remaining low probability of risks, both dietary and non-dietary human risk, as well as all environmental risks, were weighed against the potential benefits to determine whether, these remaining risks outweigh the benefits in the absence of regulatory oversight. Despite the very low level of remaining risks, and the significant potential benefits, EPA concluded that the balance between the two was extremely close. This was based on several considerations. First, the action at issue is an exemption, which could complicate EPA's ability to respond in the unlikely event a problem should arise. Moreover, the nature of the potential risks of these products themselves present particular regulatory challenges. Both the nature of the possible hazards and the exposure considerations presented by the potential for the plant's genetic material to spread to wild relatives, weigh heavily in any risk benefit balance. In addition, because it is an exemption, EPA bears the burden of both adducing the necessary evidence to support the rulemaking, and ensuring that the facts continue to support the exemption over time. Given the breadth of the exemption, EPA believed that it could not ensure over time that it could continue to support a finding that the benefits outweigh the risks in the complete absence of regulatory oversight.

But EPA does not believe that the potential risks outweigh the benefits to a degree that would warrant the pre-market approval system of registration. As described throughout this preamble, even though the nature of the risks are substantial, the probability of the risks is slight. In general, EPA believes that, given the probability of the potential risks there would be a minimal societal benefit in imposing the full degree of pre-market and post-market oversight associated with FIFRA registration. Rather, EPA believes that the imposition of the adverse effects reporting requirement, when taken with the other conditions of the FIFRA and FFDCA exemptions, tips the balance of the risks and benefits. The reporting requirement will allow the Agency to ensure that the exempted plant-incorporated protectants will continue to meet the conditions of the exemption, and will provide a mechanism to monitor the effects of this class of products. Further, because the exemption is expressly conditioned on the levels of the pesticidal substance remaining at levels that will not be injurious or deleterious to human health, EPA and FDA will be able to address the risk presented by a particular plant-incorporated protectant should a toxicant or high levels of a toxicant occur in the food supply, without the need to revoke the exemption. This permits some continuing degree of post-market oversight analogous to that provided through the registration process.

E. Establishment of 40 CFR Part 174

EPA received three comments addressing the establishment of new 40 CFR part 174. All of the comments supported the Agency's proposed rule.

As proposed in the 1994 **Federal Register** document, EPA establishes a new 40 CFR part 174. The new part will consolidate regulations specifically applicable to plant-incorporated protectants into one part of the CFR. EPA believes that establishment of a new part specifically for plant-incorporated protectants is appropriate and justified because of the characteristics that distinguish plant-incorporated protectants from other types of pesticides. This consolidation is expected to benefit the public by providing greater focus, enhanced clarity and ease of use. The regulatory requirements found in 40 CFR part 174 apply to plant-incorporated protectants only. Regulations in 40 CFR part 174 supersede other pesticide regulations found in 40 CFR parts 150 through 173 and 40 CFR parts 177 through 180 when these regulations conflict with a regulation in 40 CFR part 174. Unless otherwise superseded by 40 CFR part 174, the regulations in 40 CFR parts 150 through 173 apply to plant-incorporated protectants.

In this final rule, EPA establishes subparts in 40 CFR part 174 to contain either regulations EPA is implementing through this rule, or regulations EPA may implement in the future, tailored to apply specifically to plant-incorporated protectants. EPA has numbered and organized 40 CFR part 174 somewhat differently in this final rule than proposed in the November 23, 1994, **Federal Register** document (59 FR 60533), in part to provide greater flexibility for including future regulations at 40 CFR part 174, and for greater ease of use.

In 40 CFR part 174, subpart A, ''General Provisions,'' § 174.1 describes the scope and purpose of part 174. For clarification, some revisions have been made to the language of proposed § 174.1 as it appeared in proposed subpart A of the November 23, 1994, **Federal Register** document (59 FR 60534). Subpart A also contains at

§ 174.3 the definitions relevant to plant-incorporated protectants. As described elsewhere in this document, some definitions proposed at § 174.3 in the November 23, 1994, **Federal Register** document (59 FR 60534) were revised for clarity, to limit the exemption, and to accommodate the change of name of this type of pesticide from ''plant-pesticide'' to ''plant-incorporated protectant.'' Subpart A also describes at § 174.9 procedures for dealing with confidential business information (CBI) claims for plant-incorporated protectants.

Subpart B is established in 40 CFR part 174 and describes at § 174.21 ''General qualifications for exemptions.'' The exemption promulgated with this final rule is described at § 174.25, ''Plant-incorporated protectant derived from sexually compatible plant.'' The proposed rule in the November 23, 1994, **Federal Register** document (59 FR 60535) described the proposed exemption in proposed subpart A at § 174.5. The exemption has been described in a separate subpart B, in the final rule, to facilitate ease of use and ability to easily expand the list of exemptions.

Subpart D is established in 40 CFR part 174 for monitoring and recordkeeping requirements and sets forth requirements for submission of information regarding adverse effects caused by otherwise exempted plant-incorporated protectants. In the November 23, 1994, **Federal Register** document (59 FR 60535) the proposed language describing this proposed reporting requirement appeared at proposed 40 CFR 174.7. A subpart D has been established and the adverse effects reporting requirement has been placed at § 174.71 in subpart D to establish a distinct subpart for monitoring and recordkeeping requirements. The establishment of this subpart should facilitate ease of use by the regulated community.

Subpart C is established and reserved in 40 CFR part 174 for registration procedures and requirements. Similarly, subparts E through V are established and reserved in 40 CFR part 174 for regulations addressing other activities associated with plant-incorporated protectants; e.g., labeling, data requirements and experimental use permits. It is anticipated that future rulemakings will address these activities specifically for plant-incorporated protectants, and that the final regulations for these activities will be placed in these subparts.

Subpart W is established in 40 CFR part 174 to contain tolerances and exemptions from the requirement of a tolerance for plant-incorporated protectants under FFDCA section 408. Because 40 CFR part 174 did not exist at the time of the publication of the proposals to exempt certain categories of residues of plant-incorporated protectants (59 FR 60535, 60542, 60545) from the FFDCA requirement of a tolerance, the proposals were presented as amendments to 40 CFR part 180. With the establishment of 40 CFR part 174 through this final rule, the exemptions from the requirement of a tolerance published in companion documents elsewhere in this issue of the **Federal Register** are listed at 40 CFR 174.475, ''Nucleic acids that are part of a plant-incorporated protectant; exemption from the requirement of a tolerance'', and at § 174.479, ''Pesticidal substance derived from sexually compatible plant; exemption from the requirement of a tolerance''. Tolerances or exemptions from the requirement of a tolerance issued for plant-incorporated protectants prior to establishment of 40 CFR part 174 and thus currently listed at 40 CFR part 180 will be moved in the near future to 40 CFR part 174, subpart W. It is anticipated that establishment of subpart W in 40 CFR part 174 will facilitate ease of the use of the CFR for the general community, particularly those manufacturing and using plant-incorporated protectants.

A subpart X is established in 40 CFR part 174 and titled ''List of Approved Inert Ingredients.'' At § 174.485 EPA, EPA lists inert ingredients from sexually compatible plants.

F. Upfront Substantiation of Confidential Business Information

EPA continues to believe that substantiation of CBI claims for plant-incorporated protectants at the time of submission of information to the Agency will help to ensure a timely response to submissions for plant-incorporated protectants, further the public's right to access information and, consistent with FIFRA, protect confidential business information. EPA has concluded that up-front substantiation of CBI claims does not invalidate or jeopardize legitimate CBI claims. The Agency recognizes that the regulated community has a legitimate and legally cognizable interest in protecting trade secrets and other CBI. EPA has concluded that the requirement at 40 CFR 174.9 in the final rule allows the Agency to respond to requests for access to information, provide (where appropriate) expurgated copies of submissions and a rationale for any exclusions, and where necessary, make final determinations with respect to the validity of CBI claims without delaying regulatory action while CBI claims are being substantiated.

The release of information prior to registration is controlled in part by the Freedom of Information Act (FOIA), 5 U.S.C. 552, and section 10 of FIFRA (7 U.S.C. 136h). FOIA requires Federal agencies to provide the public with copies of agency records upon request, but contains exemptions from disclosure. Among those exemptions is one for ''trade secrets and commercial or financial information obtained from a person and privileged or confidential'' (5 U.S.C. 552(b)(4)). FIFRA section 10(b) requires protection of the same class of information. However, section 10(d)(1) limits confidentiality protection for safety and efficacy data (unless disclosure of such data in turn would disclose manufacturing or quality control processes, the method for detecting any deliberately added inert ingredient, or the identity or percentage quality of any deliberately added inert ingredient) for registered or previously registered pesticides (7 U.S.C. 136h(d)(1)). Even these excepted categories must meet the section 10(b) requirements in order to be protected. Section 3(c)(2)(A) of FIFRA provides for disclosure of certain non-confidential data 30 days after registration (7 U.S.C. 136a(c)(2)(A)).

The Agency received five comments that address the proposed requirement for up-front substantiation of CBI. Four commenters agreed with the provision. These commenters generally agreed that up-front substantiation of CBI claims will help to both ensure that the public has adequate access to information and provide timely responses to the regulated community.

One commenter disagreed with the provision for up-front substantiation of CBI. The commenter suggested that data developers would suffer substantial harm to their competitive position if data were released prematurely and asserted that EPA does not have the authority to release data to the public prior to a registration decision.

After considering these comments, EPA continues to believe that up-front substantiation of CBI claims is warranted and includes such a provision at 40 CFR 174.9. The commenter incorrectly implies that § 174.9 authorizes release of information entitled to confidential protection. All § 174.9 does is accelerate the process for determining whether information claimed as confidential is, in fact, entitled to protection under FIFRA section 10(b). Congress did not provide for absolute protection of pesticide information prior to registration; rather, it required the Agency to protect that

information which lies within the ambit of section 10(b) (7 U.S.C. 136h).

The proposed rule contained a provision that substantiations that themselves were claimed as confidential would be presumptively treated as CBI by the Agency and would not be disclosed except where ordered by a Federal court, in accordance with 40 CFR 2.205(c) (part of EPA's general confidentiality regulations at 40 CFR part 2, subpart B). This proposed provision would not have changed EPA's practice in any way; it merely echoed the pre-existing agency-wide treatment of CBI substantiations. Recently, however, the Agency proposed to amend 40 CFR 2.205(c), to eliminate the automatic protection of CBI substantiations that are themselves claimed confidential (65 FR 52684, August 30, 2000). EPA believes that such treatment of substantiations is no longer necessary to support the original purpose of the regulation, i.e., encouraging businesses to provide sufficient information to support their claims. Because the Agency is contemplating removing § 2.205(c) and because the proposed provision in 40 CFR 174.9 merely echoes the existing more general provision in § 2.205(c), the § 174.9 provision is not included in this final rule.

VIII. Documents in the Official Record

As indicated in Unit I.B.2., the official record for this rule has been established under the docket control number OPP–300369B, the public version of which is available for inspection as specified in Unit I.B.2.

A. References

The following books, articles, and reports were used in preparing this final rule and are cited in this document by the number indicated.

1. Whittaker, R. H. 1969. New concepts of kingdoms of organisms. Science, 163:150–160.

2. Environmental Protection Agency (EPA). 2000. ''Summary of public comments and EPA response on issues associated with plant-incorporated protectants (formerly plant-pesticides) for dockets OPP–300369, OPP–300370, OPP–300370A, and OPP–300369A''.

3. Cook, R. J., and C. O. Qualset. 1996. (Eds) Appropriate oversight for plants with inherited traits for resistance to pests. Institute of Food Technologists. Info@ift.org.

4. National Research Council. 2000. Genetically Modified Pest-Protected Plants: Science and Regulation. National Academy Press. Washington DC.

5. Webster's Unabridged Third New International Dictionary. 1961. Philip Babcock, Editor-in-Chief. G+C Merriam Co. Springfield Massachusetts.

6. H.R. Rep. No. 497, 94th Cong., 1st sess. 36(1975).

7. International Food Biotechnology Council. 1990. Biotechnologies and food; Assuring the safety of foods produced by genetic modification. In: Regulatory Toxicology and Pharmacology. Vol. 12. Academic Press. New York, New York.

8. Environmental Protection Agency (EPA) issue paper. 2000. Natural toxicants in food.

9. Raven, P. H., R. F. Evert, and S. E. Eichhorn. 1992. Biology of Plants. Fifth Edition. Worth Publishers, New York, New York.

10. Cook, R. J., and K. F. Baker. 1993. The nature and practice of biological control of plant pathogens. APS Press. St. Paul, Minnesota.

11. Harper, B. K., S. A. Mabon, S. M. Leffel, M. D. Halfhill, H. A. Richards, K. A. Moyer, and C. N. Steward, Jr. 1999. Green fluorescent protein as a marker for expression of a second gene in transgenic plants. Nature Biotechnology. Vol. 17: 1125–1129.

12. Hoy, M. A. 2000. Current status of biological control of insects. In: Emerging technologies for integrated pest management. Edited by G. G. Kennedy and T.B. Sutton. APS Press. St. Paul, Minnesota.

13. Hanson, M., and J. Halloran. In a letter dated February 22, 1995 on dockets OPP–300367 through OPP–300371.

14. Rissler, J., and M. Mellon. In a letter dated January 23, 1995 on dockets OPP–300367 through OPP–300371.

15. Environmental Protection Agency (EPA). Joint meeting of the EPA Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP), Subpanel on Plant-pesticides and the EPA Biotechnology Science Advisory Committee (BSAC), Subcommittee on Plant-Pesticides. January 21, 1994. Final report.

16. Wilks, H.M., A. Cortes, D. C. Emery, D. J. Halsall, A. R. Clarke and J. J. Holbrook. 1992. Opportunities and limits in creating new enzymes. In: Enzyme Engineering XI. Edited by D. S. Clark and D. A. Estell. Annals of the New York Academy of Sciences. Vol. 672. The New York Academy of Sciences. New York. New York.

17. Watson, J. D., N. H. Hopkins, J. W. Roberts, J. A. Steitz and A. M. Weiner. 1987. Molecular Biology of the Gene. Fourth Edition. The Benjamin/Cummings Publishing Company, Inc. Menlo Park, California.

18. Environmental Protection Agency (EPA) issue paper. 1994. FIFRA: Benefit and environmental risk considerations for inherent plant-pesticides.

19. World Cancer Research Fund and American Institute for Cancer Research. 1997. Food, Nutrition and the Prevention of Cancer: A Global Perspective. BANTA Book Group, Menasha, Wisconsin.

20. Lampe, J. M. 1999. Health effects of vegetables and fruit: assessing mechanisms of action in human experimental studies. American Journal of Clinical Nutrition Sep;70(3 Suppl):475S–490S.

21. Ogomoto, I. A. Shibata and K. Fukuda. 2000. World Cancer Research Fund/American Institute of Cancer Research 1997 recommendation: applicability to digestive tract cancer in Japan. Cancer Causes Control Jan;11(1):9–23.

22. Joseph, J. A., B. Shukitt-Hale, N. A. Denisova, D. Bielinski, A. Martin, J. J. McEwen and P. C. Bickford. 1999. Reversals of age-related declines in neuronal signal transduction, cognitive, and motor behavioral deficits with blueberry, spinach, or strawberry dietary supplementation. Journal of Neuroscience Sep 15;19(18):8114–21.

23. Segasothy, M. And P. A. Phillips. 1999. Vegetarian diet: panacea for modern lifestyle diseases? QJM Monthly Journal of the Association of Physicians Sep;92(9):531–44.

24. Joshipura, K. J., A. Ascherio, J. E. Manson, M. J. Stampfer, E. B. Rimm, F. E. Speizer, C. H. Hennekens, D. Spiegelman and W. C. Willett. 1999. Fruit and vegetable intake in relation to risk of ischemic stroke. Journal of American Medical Association Oct6;282(13)1233–9.

25. Thompson, H. J., J. Heimendinger, A. Haegele, S. M. Sedlacek, C. Gillette, C. O'Neill, P. Wolfe and C. Conry. 1999. Effect of increased vegetable and fruit consumption on markers of oxidative cellular damage. Carcinogenesis Dec;20(12):2261–6.

26. New, S. A., S. P. Robins, M. K. Campbell, J. C. Martin, M. J. Garton, C. Boltin-Smith, D. A. Grubb, S. J. Lee and D. M. Reid. 2000. Dietary influences on bone mass and bone metabolism: further evidence of a positive link between fruit and vegetable consumption and bone health? American Journal of Clinical Nutrition Jan;71(1):142–51.

27. Michaud, D. S., D. Spiegelman, S. K. Clinton, E. B. Rimm, W. C. Willett and E. L. Giovannucci. 1999. Fruit and vegetable intake and incidence of bladder cancer in a male prospective cohort. Journal of National Cancer Institute Apr7;91(7):605–13.

28. Association of American Feed Control Officials. Model regulations for pet food at http://

www.mindspring.com/woofsportusa/aafco.htm; Corey, B. 1991. Life on a fish farm: Food safety a priority at http://www.fda.gov/bbs/topics/CONSUMER/CONN00154.htm; Williams, G. W. And J. B. Ward. 1991 The use of cottonseed meal in animal feed rations:A survey of feed formulators at htp://agrinet.tamu.edu/tamrc/pubs/cm291.htm;

29. Agrios, George. 1988. Plant Pathology. Third edition. Academic Press, New York, New York.

30. Goodwin, T. W. and E. I. Mercer. 1983. Introduction to Plant Biochemistry. Pergamon Press. Oxford, New York, Toronto, Sydney, Paris, Frankfurt.

31. Atlas, R. and Bartha, R. 1987. Microbial Ecology. Benjamin/Cummings Publishing Company, Inc. Menlo Park, California.

32. National Resarch Council. 1999. Hormonally Active Agents in the Environment. National Academy Press, Washington DC.

33. Environmental Protection Agency (EPA) issue paper. 1994. Risk considerations for outcrossing and hybridization.

34. Doebley, J. 1988. In: ''Transgenic Plant Conference.'' Proceedings of a meeting held September 7–9, 1988, in Annapolis, Maryland. Pages 137–145. Prepared by the Keystone Center. Frisco, Colorado.

35. Lovell, C. R. 1993. Plants and the skin. First edition. Oxford, Blackwell Scientific Publications.

36. Environmental Protection Agency (EPA) issue paper. 2000. Dermal and inhalation exposure to plant substances.

37. Guy, R. H., and J. Hadgraft. 1991. Principles of skin permeability relevant to chemical exposure. In: Dermal and Ocular Toxicology: Fundamentals and Methods. Edited by D. W. Hobson. CRC Press Boca Raton, Florida.

38. Environmental Protection Agency. 1997. Exposure Factors Handbook. Volume 1. National Center for Environmental Assessment. EPA/600/P–95/002Fa.

39. Evans, L.T. 1998. Feeding the ten billion: Plants and population growth. Cambridge University Press. Cambridge, United Kingdom.

40. Conway, G. 1998. The doubly green revolution: Food for all in the 21st century. Cornell University Press, New York. Pp. 44–68.

41. Duvick D. N. 1984. Genetic contributions to yield gains of US hybrid maize, 1930 to 1980. In: Genetic contribution yield gains of five major crop plants. Edited by W. R. Fehr. Crop Science Society of America Special Publication Number 7. Madison, Wisconsin: CSSA.

42. Specht, R. F., and J. H. Williams. 1984. Contributions of genetic technology to soybean productivity – retrospect and prospect. In: Genetic contribution to yield gains of five major crop plants. Edited by W. R. Fehr. Crop Science Society of America Special Publication Number 7. Madison, Wisconsin: CSSA.

43. Huffman, W. E., and R. E. Evensen. 1993. Science for agriculture: A long term perspective. Ames: University of Iowa Press.

44. Miller, F. R., and Y. Kebede. 1984. Genetic contributions to yield gains on sorghum. In: Genetic contribution yield gains of five major crop plants. Edited by W. R. Fehr. Crop Science Society of America Special Publication Number 7. Madison, Wisconsin: CSSA.

45. Schmidt, J. W. 1984. Genetic contributions to yield gains in wheat. In: Genetic contribution yield gains of five major crop plants. Edited by W. R. Fehr. Crop Science Society of America Special Publication Number 7. Madison, Wisconsin: CSSA.

46. Feyerherm, A. M., K. E. Kemp, and G. M. Paulsen. 1988. Wheat yield analysis in relation to advancing technology in the Midwest United States. Agronomy Journal 80:998–1001.

47. Bucknell, A. and A. Moxey. 1990. Biotechnology and agriculture. Food Policy Westbury, United Kingdom, Vol. 15: 44–53.

48. Hill, L. D. and W. J. Florkowski. 1991. The economics of biotechnology in field-crop production. Illinois Research, Spring/Summer. pp. 8–10.

49. Stanley, J. A. 1991. Agricultural biotechnology: Dividends and drawbacks. Federal Reserve Bank of Kansas City. Economic Review, May/June, pp. 43–55.

50. Environmental Protection Agency (EPA). 2000. Economic analysis of the plant-incorporated protectant regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

51. Environmental Protection Agency. 1998. The Environmental Protection Agency's white paper on *Bacillus thuringiensis* plant-pesticide resistance management. EPA 739–S–98–001. (http://www.wpa.gov/fedrgstr/).

B. Additional Information

The 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)(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–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–30069A 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–300368B for the companion 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)'' (FRL–6057–6) published elsewhere in this issue of the **Federal Register**.

The docket identified by the docket control number OPP–300371B for the companion 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)'' (FRL–6057–5) published elsewhere in this issue of the **Federal Register**.

The docket identified by the docket control number OPP–300370B for the document entitled ''Plant-Incorporated Protectants; Supplemental Notice of Availability'' (FRL–6760–4).

The docket identified by the docket control number OPP–300369B for this document [FRL–6057–7].

Also include in the 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 Science Advisory Panel pertaining to the development of this final rule.
3. The Economic Analysis for this final rule, and supporting documents (Ref. 50).
4. Support documents and reports.
5. Records of all communications between EPA personnel and persons outside EPA pertaining to the final rule. (This does not include any inter-agency and intra-agency memoranda, unless specifically noted in the Indices of the dockets).
6. Published literature that is cited in this document.
7. The response to comments documents pertaining to the development of this final rule (Ref. 2).

IX. Statutory Review Requirements

In accordance with FIFRA section 25(a), this proposed rule was submitted to the FIFRA Scientific Advisory Panel, the Secretary of Agriculture (USDA), and appropriate Congressional Committees. The Scientific Advisory Panel waived its review of this final rule. Any changes made in response to comments received from USDA have been documented in the public version of the official record, along with any other comments received during the inter-agency review under Executive Order 12866.

X. Regulatory Assessment

A. Executive Order 12866

Pursuant to Executive Order 12866 (58 FR 51735, October 4, 1993), it has been 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 OMB for review, and any comments or changes made during that review have been documented in the public version of the official record for this rulemaking.

EPA has prepared an economic analysis of the impacts related to this final action, which evaluates the direct costs of regulating certain types of plant-incorporated protectants and exempting one specific type of plant-incorporated protectants from FIFRA requirements (40 CFR part 174) and discusses the non-quantifiable benefits of this action. Direct compliance costs include cost estimates for the requirements to substantiate CBI when the claim is made and adverse effects reporting for otherwise exempt plant-incorporated protectants. This economic analysis is contained in a document entitled ''Economic Analysis: Regulations for Plant-Incorporated Protectants Under the Federal Insecticide, Fungicide, and Rodenticide Act,'' hereinafter ''the EA.'' This document is available as a part of the public version of the official record for this rulemaking (Ref. 50) and is briefly summarized here. (See Unit I. for instructions on obtaining support documents).

The EA presents the potential costs and benefits associated with the various requirements considered by the Agency during the development of the final action. This rule may impose direct compliance costs of $2.4 million in year 1 and $7.9 million in year 10. The benefits include the non-quantifiable benefits of assurance of protection of the environment, a more certain regulatory climate for industry, and reassurance to the public of the safety of these products. As such, the Agency believes that the potential annual costs associated with the exemption is minimal.

The Agency's EA at the time of proposed rule in 1994 estimated and compared the costs and benefits associated with four options, ranging from implementation of regulating few types of plant-incorporated protectants with exemptions of several types of plant-incorporated protectants, through implementation of increasing numbers of types of plant-incorporated protectants regulated and decreasing the exemptions. The EA for the final rule calculates the direct compliance costs associated with four similar options. The methodology employed in both the proposed EA and the final EA is the same. The costs of each of the four options in the final EA are lower than the costs of the four options in the EA for the proposed rule. This can, in general, be attributed to an agreement between EPA and USDA that costs for data generation would not be ''double counted'', i.e., if USDA required certain data, EPA would not count the costs of that data in its EA. Based on the Agency's experience over the past several years, EPA also lowered its estimate of the probability when more expensive, higher tiered testing would for required. The Agency also increased its estimates of projected number of plant-incorporated protectants submitted annually for registration.

This rule will also generate a wide range of non-monetized benefits for the public, the firms involved with agricultural biotechnology, the environment, nontarget organisms, and states. These benefits include greater certainty in the regulated community of the status of their plant- incorporated protectant. Because EPA issued a proposal to exempt several broad categories of plant-incorporated protectants in 1994, some uncertainty may exist in industry regarding the status of many plant-incorporated protectants under FIFRA and this uncertainty may also be a cost on industry. The final rule will clarify the status of one category of plant-incorporated protectants and thereby eliminate some of this uncertainty. With this action, firms developing and testing plant-incorporated protectants can plan ahead for timely product development and commercialization, which should, in turn, attract investors to the agricultural biotechnology sector. States will benefit by having a set of standardized Federal regulations that will be more easily conveyed, interpreted, and enforced. In addition, through this rule, EPA can help reassure the public of the safety of these types of products; registrants of plant-incorporated protectants can expend the considerable resources on research and development of products which may not be accepted by the public if EPA cannot assure their safety. Industry thus benefits by a reduction of uncertainty about the acceptability of their products and by greater market acceptance of the products.

B. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U. S. C. 601 *et seq.*), the Agency hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The factual basis for the Agency's determination is presented in the small entity impact analysis prepared as part of the economic analysis for this rule (Ref. 50), and is briefly summarized here.

For the purpose of analyzing the potential impacts of this rule on small entities, EPA used the definition for

small entities that is found in section 601 of the RFA. Under section 601, ''small entity'' is defined as: (1) A small business that meets Small Business Administration (SBA) size standards codified at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. This rule is not expected to adversely impact small local governments. EPA's analysis, therefore, assesses the potential impacts on small not-for-profit organizations (i.e., universities with $5 million or less in annual revenues under the SBA size standard for SIC 8221), and small businesses i.e., small pesticides and agricultural chemical producers with 500 or less employees under SBA size standard for SIC 2879.

In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact on [...] small entities.'' 5 U.S.C. sections 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 effects on all of the small entities subject to the rule.

The aggregate potential impacts of the rule are expected to be minimal on small pesticide and other chemical manufacturers. Seed companies were not evaluated separately because the data available indicate that most seed companies have been purchased by larger, parent companies, many of which are pesticide manufacturers. The anticipated impact on universities, colleges, and professional schools cannot be determined. It appears that a majority of universities and colleges that would be expected to develop and research plant-incorporated protectants would not be small. Since small R&D firms lack the expertise and resources to produce, sell and manufacture plant-incorporated protectants, the burden of registration will not fall on specialized R&D firms. The Agency anticipates that many of the R&D firms with specialized expertise in this area will either work with or be purchased by larger firms with the expertise and financial resources to produce, sell, and/or distribute viable plant-incorporated protectants.

Information relating to this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

C. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, and included on the related collection instrument.

The information collection requirements contained in this final rule have been submitted to OMB for review and approval under the PRA in accordance with the procedures at 5 CFR 1320.11. The burden and costs related to the information collection requirements contained in this rule are described in an Information Collection Request (ICR) identified as EPA ICR No. 1693.02, which has been included in the public version of the official record described in Unit I.B.2., and is available electronically as described in Unit I.B.1., at http://www.epa.gov/opperid1/icr.htm, or by e-mailing a request to farmer.sandy@epa.gov. You may also request a copy by mail from Sandy Farmer, Collection Strategies Division, U.S. Environmental Protection Agency (Mail Code 2822), 1200 Pennsylvania Ave. NW., Washington, DC 20460, or by calling (202) 260–2740.

As defined by the PRA and 5 CFR 1320.3(b), ''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 for rule familiarization and to review instructions; develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The information collection requirements contained in this rule include up-front substantiation for claims of CBI for plant-incorporated protectant activities (e.g., EUP submissions, registration applications, tolerance requests, and adverse effects reporting), and for adverse effects reporting for the otherwise exempt plant-incorporated protectants. The annual respondent burden associated with the CBI substantiation and averse effects reporting for exempted plant-incorporated protectants is estimated to average 352 hours per submission, with a potential individual respondent burden of 25 hours for each CBI substantiation required, and 7.8 hours for each adverse effects reporting event. The annual respondent burden associated with the CBI substantiation for those plant-incorporated protectants that are not exempted by this rule is estimated to be 595 hours.

D. Unfunded Mandates Reform Act

Pursuant to 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 for State, local or tribal governments, in the aggregate, or on the private sector in any one year. The analysis of the costs associated with this action are described in Unit X.A.

The UMRA requirements in sections 202, 204, and 205 do not apply to this rule, because this action does not contain any ''Federal mandates'' or impose any ''enforceable duty'' on State/Tribal, or local governments or on the private sector. The requirements in section 203 do not apply because this rule does not contain any regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.''

This final 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 pesticides from most FIFRA requirements. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

F. Executive Orders 13084 and 13175

This rule does not significantly or uniquely affect the communities of Indian tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), do not apply to this rule. Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), which took effect on January 6, 2001, revokes Executive Order 13084 as of that date. EPA developed this rulemaking, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13084. For the same reasons stated for Executive Order 13084, the requirements of Executive Order 13175 do not apply to this rule either.

G. Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629, February 11, 1994), entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*, the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities. The Agency is required to consider the potential for differential impacts on sensitive sub-populations. EPA considered available information on the sensitivities of subgroups as pertains to the exemptions. EPA concluded that no subgroup would be differentially affected. (See also the exemptions from the FFDCA section 408 requirement of a tolerance for residues of nucleic acids that are part of a plant-incorporated protectant and residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants published elsewhere in companion documents in this issue of the **Federal Register**).

H. Executive Order 13045

Executive Order 13045, entitled: *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), does not apply to this rule because it is not economically significant as defined in section 3(f) of Executive Order 12866, and because the Agency does not have reason to believe that the environmental health or safety risks addressed by this action present disproportionate risks to children. The Agency has determined that the plant-incorporated protectants exempted in the rule pose only a low probability of risk to human health, including the health of infants and children, and that there is a reasonable certainty no harm will result to infants and children from aggregate exposure to residues of these plant-incorporated protectants in food. Existing information suggests there are no disproportionate effects on infants or children from dietary or other exposures. EPA's assessment and the results of its assessment for infants and children are contained in Unit IX.B.10. of companion documents published elsewhere in this issue of the **Federal Register** exempting from the FFDCA section 408 requirement of a tolerance, residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants, and residues of nucleic acids that are part of a plant-incorporated protectant.

I. Voluntary Consensus Standards

This rule does not involve a regulatory action that would require the Agency to consider voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (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. Voluntary consensus 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 12630

EPA has complied with Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988), by examining the takings implications of this rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the Executive Order.

K. Executive Order 12988

In issuing this rule, EPA has taken the 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, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

L. FIFRA section 25(a)(2)(b)

FIFRA section 25(a)(2)(b), requires that the Administrator of EPA consider such factors as ''. . . the effect of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. . .'' when issuing regulations under section 25 (7 U.S.C. 136w(a)(2)(B). The total direct compliance costs for the rule were estimated to be $2.4 in year 1 and $7.9 in year 10. Based on the 1997 Agricultural Census, total U.S. crop production was valued at $98 billion. The impact of these requirements will not have a significant impact on U.S. crop production or prices. The compliance costs of the rule will affect those who plan to register, manufacture and sell plant-incorporated protectants. This rule is expected to have a minimal impact on pesticide and other chemical manufacturers who in turn will sell the plant-incorporated protectants to agricultural producers. Factors, other than this rule, that occur as a result of the production of genetically altered products (i.e., consumer acceptance and the international market desire to separately market genetically altered products in the market) may affect agricultural producers and international markets. This rule may provide some benefits to the agricultural industry by helping to ensure the public on the safety of these products and positively affect consumer acceptance.

M. 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 this action is not expected to affect energy supply, distribution, or use.

XI. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Parts 152 and 174

Environmental protection, Administrative practice and procedures, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 12, 2001.

Christine T. Whitman,

Administrator.

Therefore, 40 CFR chapter I is amended as follows:

1. By amending part 152 as follows:

PART 152—[AMENDED]

a. The authority citation for part 152 continues to read as follows:

Authority: 7 U.S.C. 136–136y; subpart U is also issued under 31 U.S.C. 9701.

b. § 152.1 is revised to read as follows:

§ 152.1 Scope.

Except as provided in part 174, part 152 sets forth procedures, requirements, and criteria concerning the registration and reregistration of pesticide products under FIFRA sec. 3, and for associated regulatory activities affecting registration. These latter regulatory activities include data compensation and exclusive use (subpart E), and the classification of pesticide uses (subpart I). Part 152 also sets forth procedures, requirements, and criteria applicable to plant-incorporated protectants. Unless specifically superceded by part 174, the regulations in part 152 apply to plant-incorporated protectants.

c. In § 152.3, by removing the paragraph designations, alphabetizing the terms, alphabetically inserting the new definitions listed below, and revising the definitions for ''active ingredient'' and ''inert ingredient'' to read as follows:

§ 152.3 Definitions.

* * * * *

Active ingredient means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a), except as provided in § 174.3 of this chapter.

* * * * *

Genetic material necessary for the production means both: Genetic material that encodes a substance or leads to the production of a substance, and regulatory regions. It does not include noncoding, nonexpressed nucleotide sequences.

In a living plant means inside the living plant, on the surface of the livingplant, or as an exudate from the living plant.

Inert ingredient means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product, except as provided by § 174.3 of this chapter.

* * * * *

Living plant means a plant, plant organ, or plant part that is alive, viable, ordormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems,flowers, and pollen.

* * * * *

Noncoding, nonexpressed nucleotide sequences means the nucleotidesequences are not transcribed and are not involved in gene expression. Examples of noncoding,nonexpressed nucleotide sequences include, but are not limited to, linkers, adapters, homopolymers, and sequences ofrestriction enzyme recognition sites.

* * * * *

Pesticidal substance, when referring to a plant-incorporatedprotectant only, means a substance that is intended to be produced and used in a living plant, or inthe produce thereof, for a pesticidal purpose during any part of a plant's life cyle (e.g., in theembryo, seed, seedling, mature plant).

Plant-incorporated protectant means a pesticidal substance that isintended to be produced and used in a living plant, or in the produce thereof, and the geneticmaterial necessary for production of such a pesticidal substance. It also includes any inertingredient contained in the plant, or produce thereof.

Produce thereof, when referring to plant-incorporated protectantsonly, means a product of a living plant containing a plant-incorporated protectant, where thepesticidal substance is intended to serve a pesticidal purpose after the product has been separatedfrom the living plant. Examples of such products include, but are not limited to, agriculturalproduce, grains, and lumber. Products such as raw agricultural commodities bearing pesticidechemical residues are not ''produce thereof'' when the residues are not intended to serve apesticidal purpose in the produce.

Regulatory region means genetic material that controls theexpression of the genetic material that encodes a pesticidal substance or leads to the production ofa pesticidal substance. Examples of regulatory regions include, but are not limited to, promoters, enhancers, andterminators.

* * * * *

d. In § 152.20, by revising paragraph (a)(1) and adding paragraph (a)(4)to read as follows:

§ 152.20 Exemptions for pesticidesregulated by another Federal agency.

* * * * *

(a) * * *

(1) Except as provided by paragraphs (a)(3) and (a)(4) of this section, all biologicalcontrol agents are exempt from FIFRA requirements.

* * * * *

(4) All living plants intended for use as biological control agents are exempt from therequirements of FIFRA. However, plant-incorporated protectants are not exempt pursuant to thissection. Regulations, including exemptions, for plant-incorporated protectants are addressed inpart 174 of this chapter.

* * * * *

2. By adding a new part 174 to read as follows:

PART 174—PROCEDURES AND REQUIREMENTS FORPLANT-INCORPORATED PROTECTANTS

Subpart A—General Provisions

Sec.

174.1 Scope and purpose.

174.3 Definitions.

174.9 Confidential business information claims for plant-incorporated protectant submissions.

Subpart B—Exemptions

174.21 General qualifications for exemptions.

174.25 Plant-incorporated protectant from sexually compatibleplant.

Subpart C—Registration Procedures and Requirements [Reserved]

Subpart D—Monitoring and Recordkeeping

174.71 Submission of information regarding adverse effects.

Subparts E—F [Reserved]

Subpart G—Labeling Requirements [Reserved]

Subpart H—Data Requirements [Reserved]

Subpart I—[Reserved]

Subpart J—Good Laboratory Practices [Reserved]

Subpart K—Export Requirements [Reserved]

Subparts L—T [Reserved]

Subpart U—Experimental Use Permits [Reserved]

Subpart V—[Reserved]

Subpart W—Tolerances and Tolerance Exemptions

174.451 Scope and purpose.

Subparts X—List of Approved Inert Ingredients

174.480 Scope and purpose.
174.485 Inert ingredients from sexually compatible plant.

Subpart Y—Z [Reserved]

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 346a and 371.

Subpart A—General Provisions

§ 174.1 Scope and purpose.

The characteristics of plant-incorporated protectants such as their production and use inplants, their biological properties, and their ability to spread and increase in quantity in theenvironment distinguish them from traditional chemical pesticides. Therefore, plant-incorporatedprotectants are subject to some different regulatory requirements and procedures than traditionalchemical pesticides. This part sets forth regulatory requirements, criteria, and proceduresapplicable to plant-incorporated protectants under FIFRA and FFDCA. When applied toplant-incorporated protectants, the definitions and regulations in this part supercede theregulations found in parts 150 through 180 of this chapter to the extent that the regulationsconflict. Unless otherwise superceded by this part, the regulations in parts 150 through 180 of thischapter apply to plant-incorporated protectants.

§ 174.3 Definitions.

Terms used in this part have the same meaning as in FIFRA. In addition, the following termshave the meaning set forth in this section.

*Active ingredient*means a pesticidal substance that is intended to be produced and used in a living plant, or in theproduce thereof, and the genetic material necessary for the production of such a pesticidalsubstance.

Administrator means the Administrator of the United States EnvironmentalProtection Agency or his/her delegate.

Bridging crosses between plants means the utilization of anintermediate plant in a cross to produce a viable zygote between the intermediate plant and a firstplant, in order to cross the plant resulting from that zygote with a third plant that would nototherwise be able to produce viable zygotes from the fusion of its gametes with those of the firstplant. The result of the bridging cross is the mixing of genetic material of the first and third plantthrough the formation of an intermediate zygote.

Cell fusion means the fusion *in vitro* of two ormore cells or protoplasts.

Conventional breeding of plants means the creation of progenythrough either: The union of gametes, i.e., syngamy, brought together through processes such aspollination, including bridging crosses between plants and wide crosses, or vegetative reproduction. It does not include use of any of the following technologies: Recombinant DNA;other techniques wherein the genetic material is extracted from an organism and introduced intothe genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion.

EPA means the United States Environmental Protection Agency.

Exudate means a substance gradually discharged or secreted acrossintact cellular membranes or cell walls and present in the intercellular spaces or on the exteriorsurfaces of the plant.

FFDCA means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321*et seq.*).

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, asamended (7 U.S.C. 136 *et seq.*).

Food includes articles used for food or drink by humans or otheranimals.

Food plant means a plant which either in part or *intoto*, is used as food.

Genetic material necessary for the production means both: Genetic material that encodes a substance or leads to the production of a substance; and regulatory regions. It does not include noncoding, nonexpressed nucleotide sequences.

Genome means the sum of the heritable genetic material in the plant, including genetic material in the nucleus and organelles.

In a living plant means inside the living plant, on the surface of the livingplant, or as an exudate from the living plant.

Inert ingredient, means any substance, such as a selectable marker, other than the active ingredient, where thesubstance is used to confirm or ensure the presence of the active ingredient, and includes the geneticmaterial necessary for the production of the substance, provided that genetic material isintentionally introduced into a living plant in addition to the active ingredient.

Living plant means a plant, plant organ, or plant part that is alive, viable, ordormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems,flowers, and pollen.

Noncoding, nonexpressed nucleotide sequences means the nucleotidesequences are not transcribed and are not involved in gene expression. Examples of noncoding,nonexpressed nucleotide sequences include, but are not limited to, linkers, adapters, homopolymers, and sequences ofrestriction enzyme recognition sites.

Nucleic acids means 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 asdeoxyribonucleic 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 containingnucleic acid analogues.

Pesticidal substance, means a substance that is intended to be produced and used in a living plant, orin the produce thereof, for a pesticidal purpose, during any part of a plant's life cyle (e.g., in theembryo, seed, seedling, mature plant).

Plant, for plant-incorporated protectants, means an organismclassified using the 5-kingdom classification system of Whittaker in the kingdom Plantae. Thisincludes, but is not limited to, bryophytes such as mosses, pteridophytes such as ferns,gymnosperms such as conifers, and angiosperms such as most major crop plants.

Plant-incorporated protectant means a pesticidal substance that is intendedto be produced and used in a living plant, or in the produce thereof, and the genetic materialnecessary for production of such a pesticidal substance. It also includes any inert ingredientcontained in the plant, or produce thereof.

Produce thereof, when used with respect to plants containing plant-incorporated protectants only, means a product of a living plant containing a plant-incorporatedprotectant, where the pesticidal substance is intended to serve a pesticidal purpose after theproduct has been separated from the living plant. Examples of such products include, but are notlimited to, agricultural produce, grains, and lumber. Products such as raw agriculturalcommoditiesbearing pesticide chemical residues are not ''produce thereof'' when the residues are not intendedto serve a pesticidal purpose in the produce.

Recipient plant means the living plant in which theplant-incorporated protectant is intended to be produced and used.

Recombinant DNA means the genetic material has been manipulated*in vitro* through the use of restriction endonucleases and/or other enzymes that aid in modifyinggenetic material, and subsequently introduced into the genome of the plant.

Regulatory region means genetic material that controls theexpression of the genetic material that encodes a pesticidal substance or leads to the production ofa pesticidal substance. Examples of regulatory regions include, but are not limited to, promoters, enhancers, andterminators.

Sexually compatible, when referring to plants, means a viable zygoteis formed only through the union of two gametes through conventional breeding.

Source means the donor of the genetic material that encodes apesticidal substance or leads to the production of a pesticidal substance.

Vegetative reproduction means either:

(1) In seed plants, reproduction by apomixis, or

(2) In other plants, reproduction by fragmentation, or division of the somatic body.

Wide crosses means to facilitate the formation of viable zygotesthrough the use of surgical alteration of the plant pistil, bud pollination, mentor pollen,immunosuppressants, *in vitro* fertilization, pre-pollination and post-pollination hormone treatments,manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures.

§ 174.9 Confidential businessinformation claims for plant-incorporated protectant submissions.

Although it is strongly recommended that the submitter minimize the amount of dataand other information claimed as Confidential Business Information (CBI), a submitter may asserta claim of confidentiality for all or part of the information submitted to EPA in a submission for aplant-incorporated protectant. (See part 2, subpart B of this chapter.) To assert such a claim, thesubmitter must comply with all of the following procedures:

(a) Any claim of confidentiality must accompany the information at the time theinformation is submitted to EPA. Failure to assert a claim at that time constitutes a waiver ofconfidentiality for the information submitted, and the information may be made available to thepublic, subject to section 10(g) of FIFRA, with no further notice to the submitter.

(b) Any claim of confidentiality must be accompanied, at the time the claim is made,by comments substantiating the claim and explaining why the submitter believes that theinformation should not be disclosed. The submitter must address each of the points listed in§ 2.204(e)(4) of this chapter in the substantiation. EPA will consider incomplete allplant-incorporated protectant submissions containing information claimed as CBI that are notaccompanied by substantiation, and will suspend any applicable review of such submissionsuntil the required substantiation is provided.

Subpart B—Exemptions

§ 174.21 General qualifications forexemptions.

A plant-incorporated protectant is exempt from the requirements of FIFRA, other than therequirements of § 174.71, if it meets all of the following criteria:

(a) The plant-incorporated protectant meets the criteria listed in at least one of thesections in § § 174.25 through 174.50.

(b) When the plant-incorporated protectant is intended to be produced and used in acrop used as food, the residues of the plant-incorporated protectant are either exempted from therequirement of a tolerance under FFDCA (as amended, 21 U.S.C. 321 *et seq.*) ascodified at § § 174.475 through 174.479, or no tolerance wouldotherwise be required for the plant-incorporated protectant.

(c) Any inert ingredient that is part of the plant-incorporated protectant is on the listcodified at § § 174.485 through 174.490.Plant-incorporated protectants that are not exempt from the requirements of FIFRA under thissubpart are subject to all the requirements of FIFRA.

§ 174.25 Plant-incorporated protectantfrom sexually compatible plant.

A plant-incorporated protectant is exempt if all of the following conditions are met:

(a) The genetic material that encodes the pesticidal substance or leads to theproduction of the pesticidal substance is from a plant that is sexually compatible with the recipientplant.

(b) The genetic material has never been derived from a source that is not sexuallycompatible with the recipient plant.

Subpart C—Registration Procedures and Requirements [Reserved]

Subpart D—Monitoring and Recordkeeping

§ 174.71 Submission of informationregarding adverse effects.

(a) Any person who produces, for sale or distribution, a plant-incorporated protectantexempt under subpart B of this part, who obtains any information regarding adverse effects onhuman health or the environment alleged to have been caused by the plant-incorporated protectantmust submit such information to EPA. This requirement does not apply to any person who does not produce a plant-incorporated protectant exempt under supart B of this part. This may include, for example, researchers performing field experiments, breeders making crosses among plant varieties with the goal of developing new plant varieties, or a person who only sells propagative materials (e.g., seed) to farmers without producing the propagative materials themselves. EPA must receive the report within 30 calendar days of thedate the producer first possesses or knows of the information.

(b) Adverse effects on human health or the environment for purposes of plant-incorporated protectant means at a minimum information about incidents affecting humans orother nontarget organisms where both:

(1) The producer is aware, or has been informed, that a person or nontarget organismallegedly suffered a toxic or adverse effect due to exposure to (e.g., ingestion of) a plant-incorporated protectant.

(2) The producer has or could reasonably obtain information concerning where theincident occurred.

(c) All of the following information, if available, must be included in a report.

(1) Name of reporter, address, and telephone number.

(2) Name, address, and telephone of contact person (if different than reporter).

(3) Description of incident.
(4) Date producer became aware of incident.
(5) Date of incident.
(6) Location of incident.
(d) Mail reports and questions to: Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460 or deliver reports and questions to: Crystal Mall #2, Room 910, 1921 Jefferson Davis Hwy., Arlington, VA.

Subparts E—F [Reserved]

Subpart G—Labeling [Reserved]

Subpart H—Data Requirements [Reserved]

Subpart I—[Reserved]

Subpart J—Good Laboratory Practices [Reserved]

Subpart K—Export Requirements [Reserved]

Subparts L—T [Reserved]

Subpart U—Experimental Use Permits [Reserved]

Subpart V—[Reserved]

Subpart W–Tolerances and Tolerance Exemptions

§ 174.451 Scope and purpose.

This subpart lists the tolerances and exemptions from the requirement of a tolerancefor residues of plant-incorporated protectants in or on raw agricultural commodities, in food, andin animal feeds.

Subpart X—List of Approved Inert Ingredients

§ 174.480 Scope and purpose.

This subpart lists the inert ingredients that have been exempted from FIFRA andFFDCA section 408 requirements and may be used in a plant-incorporated protectant listed insubpart B of this part.

§ 174.485 Inert ingredients from sexually compatible plant.

An inert ingredient, and residues of the inert ingredient, are exempt if all of the following conditions are met:
(a) The genetic material that encodes the inert ingredient or leads to the production of the inert ingredient is derived from a plant sexually compatible with the recipient food plant.
(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.
(c) The residues of the inert ingredient are not present in food from the plant at levels that are injurious or deleterious to human health.

Subparts Y—Z [Reserved]

[FR Doc. 01–17981 Filed 7–16–01; 11:42 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[OPP–300371B; FRL–6057–5]

RIN 2070–AC02

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)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The substances plants produce for protection against pests, and the genetic material necessary to produce these substances, are pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if humans intend to use these substances for ''preventing, destroying, repelling or mitigating any pest.'' These substances, produced and used in living plants, along with the genetic material necessary to produce them, are also ''chemical pesticide residues'' under the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA calls these substances along with the genetic material necessary to produce them, ''plant-incorporated protectants.'' In this final rule, EPA exempts from the FFDCA section 408 requirement of a tolerance, residues of nucleic acids that are part of a plant-incorporated protectant. Nucleic acids are ubiquitous in all forms of life, have always been present in human and domestic animal food and are not known to cause any adverse health effects when consumed as part of food. EPA believes there is a reasonable certainty that no harm will result from aggregate exposure to residues of nucleic acids that are part of a plant-incorporated protectant.

DATES: This regulation is effective September 17, 2001. Objections and requests for hearings must be received by EPA on or before September 17, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by regular mail, electronically, or in person. Follow the detailed instructions for the regular mail and in person methods in Unit II. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: By mail: Philip Hutton, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs (7511C), Environmental Protection Agency, 1921 Jefferson Davis Highway, Arlington, VA 22202; telephone number: (703) 308–8260; e-mail address: hutton.phil@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 plant-incorporated protectants. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Pesticide manufacturers	32532	Establishments primarily engaged in the formulation and preparation of agricultural and household pest control chemicals
Seed companies	111	Establishments primarily engaged in growing crops, plants, vines, or trees and their seeds

Categories	NAICS codes	Examples of potentially affected entities
Colleges, universities, and professional schools	611310	Establishments of higher learning which are engaged in development and marketing of plant-incorporated protectants
Establishments involved in research and development in the life sciences	54171	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 above could also be affected. The North American Industrial Classification System (NAIC) 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. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. To access information about the EPA's program for biopesticides go directly to the Home Page for the Office of Pesticide Programs at http://www.epa.gov/pesticides/biopesticides.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300371B. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the Food Quality Protection Act (FQPA), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(e) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300371B in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 17, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the

Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit II., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–300371B, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

III. Under What Authority is EPA Issuing this Final Rule?

This exemption from the requirement of a tolerance is being issued under the authority of section 408(c) of the FFDCA (21 U.S.C. 346a(c)). 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 other 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 the 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 a commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical'' (21 U.S.C. 321(q)(2)). The 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)). 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'' with certain exceptions (7 U.S.C. 136(t)).

Under FFDCA section 408(c), EPA can establish an exemption from the requirement of a tolerance for a ''pesticide chemical residue'' only if EPA determines that granting such an exemption is ''safe'' (21 U.S.C. 346a(c)(2)(A)(i)). The 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'' (21 U.S.C. 346a(c)(2)(A)(ii)). This includes exposure through drinking water, and residential and other indoor uses, but does not include occupational exposure. In establishing an exemption from the requirement of a tolerance, FFDCA section 408(c) does not authorize EPA to consider potential benefits associated with use of the pesticide chemical in determining whether the pesticide chemical may be exempted.

FFDCA section 408 requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption 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'' (21 U.S.C. 346a(b)(2)(C)(ii)(I) and (c)(2)(B)). FFDCA section 408(b)(2)(D) specifies other general factors EPA must consider in establishing an exemption. FFDCA section 408(c)(3) prohibits an exemption unless there is either a practical method for detecting and measuring levels of pesticide chemical residue in or on food or there is no need for such a method, requiring EPA to state the reason for this determination (21 U.S.C. 346a(c)(3)).

IV. Context

A. What Role Does this Final Exemption Play in EPA's Approach toPlant-Incorporated Protectants?

The substances plants produce for protection against pests are pesticides under the FIFRA definition of pesticide, if humans intend to use these substances for ''preventing, destroying, repelling or mitigating any pest.'' These substances, produced and used in living plants, along with the genetic material necessary to produce them, are designated ''plant-incorporated protectants'' by EPA.

To understand the pivotal role this exemption plays in EPA's approach to plant-incorporated protectants, the two following considerations must be understood. First, the role nucleic acids

play in the concept of plant-incorporated protectant and how this exemption from the FFDCA requirement of a tolerance relates to this role. Second, how this exemption relates to the exemption from the FFDCA requirement of a tolerance published elsewhere in a companion document in this issue of the **Federal Register** for residues of the substance portion of plant-incorporated protectants derived through conventional breeding from sexually compatible plants.

1. *What role do nucleic acids play in the concept of plant- incorporated protectant and how does this role relate to this exemption?* The genetic material necessary for the production of a pesticidal substance is included in the definition of plant-incorporated protectant because the genetic material meets, in and of itself, the FIFRA section 2 definition of pesticide. A thorough discussion of why the genetic material is included in the definition of plant-incorporated protectant can be found in a companion document published elsewhere in this issue of the **Federal Register** on FIFRA regulations for plant-incorporated protectants.

As noted in Unit III., section 408 of FFDCA applies to residues of pesticides in or on food or feed. (Hereafter, EPA will use the term ''in food'' in the preamble to represent the concept of ''in or on food or feed.'') Under section 408 of the FFDCA, the term residue is applied broadly to include residues of the pesticide itself and residues that are present in the food as a result of the metabolism or other degradation of the pesticide. EPA anticipates that for plant-incorporated protectants, the residues will consist of the pesticidal substance and any inert ingredient as defined for plant-incorporated protectants (e.g., any selectable marker), and the genetic material necessary for production of the pesticidal substance and any inert ingredient. In instances where the pesticidal substance is a nucleic acid (e.g., satellite RNA from plant viruses), EPA anticipates these residues will be the nucleic acid functioning as the pesticidal substance and the nucleic acid comprising the genetic material necessary for the production of the pesticidal substance (as well as any inert ingredient and the genetic material necessary to produce the inert ingredient). For anti-sense technology, EPA anticipates that these residues will consist of the the anti-sense RNA, and the DNA encoding the anti-sense RNA (as well as any inert ingredient and the genetic material necessary to produce the inert ingredient).

In developing its approach to plant-incorporated protectants, EPA recognized that nucleic acids are ubiquitous in all forms of life, including food plants. There is a long history of consumption by humans of nucleic acids in food and the Agency knows of no instance where nucleic acids have been associated with any toxic effects related to the consumption of food. It is therefore appropriate to exempt residues of nucleic acids that are part of a plant-incorporated protectant from the FFDCA section 408 requirement of a tolerance.

For EPA to exempt any residue of a pesticide, including any residue of a plant-incorporated protectant, from regulation under FFDCA section 408(e), EPA must find that there is a reasonable certainty that no harm will result from aggregate exposure to the residues, including all anticipated dietary exposures and all other exposures, for which there is realiable information. EPA is exempting in this action residues of nucleic acids that are part of plant-incorporated protectant active and inert ingredients, because it has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the residues, including all anticipated dietary exposures and all other exposures for which there is reliable information. This exemption from the requirement of a tolerance applies to the nucleic acid portion of all plant-incorporated protectants.

2. *How does this exemption relate to the exemption from the FFDCA requirement of a tolerance for the substance portion of plant-incorporated protectants derived through conventional breeding from sexually compatible plants?* This exemption can be paired with EPA's decision, published elsewhere in a companion document in this issue of the **Federal Register**, to exempt residues of pesticide chemical residues derived through conventional breeding from sexually compatible plants.

Because of these actions, all residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants are exempt from FFDCA section 408 requirements.

B. Does this Final Rule Have Any Relevance to Other Types of Pesticides?

Nonviable plant tissues, organs or parts that are used as pesticides, will not be covered by this exemption. Residues of such pesticides are subject to the regulations found in 40 CFR parts 177 through 180 rather than 40 CFR part 174. An example of this type of pesticide would be the powder, produced by drying and grinding cayenne pepper, dusted on plants to protect them from pests.

Residues of substances that are isolated from a plant's tissues and then applied to plants and/or to food for pest control will not be covered by this exemption. Residues of these types of pesticides in formulations such as those for foliar application are subject to regulations found in 40 CFR parts 177 through 180 rather than 40 CFR part 174. An example of this type of pesticide would be pyrethrum isolated from chrysanthemum plants, formulated with other ingredients for foliar application, and sprayed onto other plants for pest control.

Residues of substances that are synthesized will not be covered by this exemption. Residues of such pesticides are subject to regulations found in 40 CFR parts 177 through 180 rather than 40 CFR part 174. An example of this type of pesticide is the herbicide atrazine.

C. What is the History of this Final Rule?

This final rule is an additional step in fully implementing the ''Coordinated Framework for Regulation of Biotechnology'' of the United States of America which was published in the **Federal Register** by the Office of Science and Technology Policy (OSTP) on June 26, 1986 (51 FR 23302).

EPA sponsored, or cosponsored with other Federal agencies, three conferences dealing with plant related issues: On October 19–21, 1987, a meeting on ''Genetically Engineered Plants: Regulatory Considerations'' at Cornell University, 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. Information from these conferences has been incorporated as appropriate in development of this final rule.

In developing its approach to plant-incorporated protectants, EPA requested the advice of two scientific advisory groups in three meetings. On December 18, 1992, pursuant to section 25 of FIFRA, a subpanel of the FIFRA Scientific Advisory Panel (SAP) was convened to review a draft policy on plant-pesticides (now called plant-incorporated protectants) and to respond to a series of questions posed by the Agency primarily on 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 approaches to plant-pesticides under FFDCA. On January 21, 1994, a

joint meeting of the subpanel of the SAP and the BSAC Subcommittee was held and EPA asked advice on EPA's approach to plant-pesticides under both statutes. Advice from these scientific advisory groups was considered in finalizing this final rule.

EPA published in the November 23, 1994 **Federal Register**, a package of five separate documents (59 FR 60496, 60519, 60535, 60542 and 60545) (FRL–4755–2, FRL–4755–3, FRL–4755–4, FRL–4755–5, FRL–4755–8) which described EPA's policy and proposals for plant-pesticides under FIFRA and FFDCA.

On July 22, 1996, EPA published a supplemental document in the **Federal Register** (61 FR 37891) (FRL–5387–4) on one aspect of its November 23, 1994, **Federal Register** document, i.e., how the concept of inert ingredient related to plant-pesticides.

In August of 1996, Congress enacted the FQPA which amended FFDCA and FIFRA. On May 16, 1997, EPA published in the **Federal Register** a supplemental document (62 FR 27132) (FRL–5717–2) 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 nucleic acids that are part of a plant-pesticide.

On April 23, 1999, EPA published a supplemental document (64 FR 19958) (FRL–6077–6) in the **Federal Register** soliciting comment on whether to change the name of this type of pesticide.

The documents and the reports of the meetings described above are available in the official record for the rulemaking as described in Unit X.

V. What are the Key Features of the Proposed Exemption?

The development of this exemption consists of a proposed rule that appeared in the November 23, 1994, **Federal Register** (59 FR 60542) and two supplemental documents; one document that appeared in the July 22, 1996, **Federal Register** (61 FR 37891) and a second document that appeared in the May 16, 1997, **Federal Register** (62 FR 27142).

A. November 23, 1994, **Federal Register** *Proposed Rule*

In the November 23, 1994, **Federal Register** document, EPA proposed at 40 CFR 180.1138 to exempt residues of nucleic acids that are part of a plant-pesticide (now called a plant-incorporated protectant) from the requirement of a tolerance (59 FR 60542). Specifically, EPA proposed that ''residues of nucleic acids produced in living plants as part of a plant-pesticide active or inert ingredient, including both deoxyribonucleic and ribonucleic acids,'' would be exempt from the requirement of a tolerance. ''Nucleic acids'' were described as ''ribosides or deoxyribosides of adenine, thymine, guanine, cytosine, and uracil and the polymers of these ribosides and deoxyribosides and does not apply to nucleic acid analogues.''

''Active ingredient,'' when referring to plant-incorporated protectants only, was described as ''a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.''

''Inert ingredient,'' when referring to plant-incorporated protectants only, was described as ''any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient.''

The proposal to exempt nucleic acids that are part of a plant-incorporated protectant from the requirement of a tolerance was based on the ubiquity of nucleic acids in human and domestic animal food and the consumption of food containing nucleic acids without observed adverse health effects. Nucleic acids are widespread in foods and as part of a balanced diet, do not have toxic or pathogenic effects on animals or humans.

EPA also addressed in the proposal the status of nucleic acids used in anti-sense technology. In the proposal, EPA stated its belief that nucleic acids involved in this technology would qualify for the proposed exemption. The rationale used in the proposal to support exemption of naturally-occurring nucleic acids applies to nucleic acids used in anti-sense technology, as the anti-sense RNA and DNA are composed of the same naturally-occurring nucleic acids commonly found in living cells (ribosides or deoxyribosides of cytosine, guanine, adenine, thymine, and uracil).

In 1994, the Agency clearly stated that it was not proposing to exempt nucleic acid analogues from the requirement of a food tolerance. Certain nucleic acid analogues are being developed as therapeutic agents for human diseases (e.g., dideoxycytidine) and nucleic acid analogues could conceivably be developed and used as pesticides. These analogues are not naturally-occurring and those used as therapeutic agents frequently have significant toxicity associated with their use. The intent of EPA's 1994 proposal was to exempt only the naturally-occurring nucleic acids (ribosides or deoxyribosides of cytosine, guanine, adenine, uracil, and thymine) and polymers of such substances commonly found in living cells that serve as the mechanism of encoding traits associated with pesticidal substances produced by plants. The risk assessment supporting exemption for naturally-occurring nucleic acids does not support exemption of nucleic acid analogues (e.g., dideoxycytidine), or polymers containing such analogues.

B. What Issues Were Discussed in the Supplemental Documents?

1. *July 22, 1996*. On July 22, 1996, EPA published a supplemental document in the **Federal Register** (61 FR 37891) on one aspect of its November 23, 1994, **Federal Register** document, i.e., how the concept of inert ingredient related to plant-incorporated protectants.

2. *May 16, 1997*. In August of 1996, FFDCA and FIFRA were amended by the FQPA. On May 16, 1997, EPA published in the **Federal Register**, a supplemental document (62 FR 27142) to provide the public with an opportunity to comment on EPA's analysis of how certain FQPA amendments to FFDCA and FIFRA affect the proposed exemption from the requirement of a tolerance for residues of nucleic acids that are part of a plant-incorporated protectant.

EPA stated in the May 16 document its belief that most of the substantive factors that the FFDCA now requires EPA to consider in evaluating pesticides were considered when it proposed the exemption (59 FR 60542, November 23, 1994). EPA, thus, in the supplemental document, specifically sought comment only on its evaluation of the requirements imposed by FQPA that the Agency had not addressed in the proposal. EPA sought comment on the following five considerations. First, EPA's conclusion that there are no substances outside of the food supply that may have a cumulative toxic effect with residues of nucleic acids produced in plants as part of a plant-incorporated protectant. Second, EPA's conclusion that there are no additional substances outside the food supply that are related, via a common mechanism of toxicity, to residues of nucleic acids produced in plants as part of a plant-incorporated protectant, for which EPA must consider exposure in aggregate with

nucleic acids. Third, commenters who possess information on nucleic acids causing estrogenic effects were requested to send such information to EPA. Fourth, EPA described in greater detail the rationale supporting the statement made in the 1994 **Federal Register** document (59 FR at 60513) that ''plant-pesticides are likely to present a limited exposure of pesticidal substances to humans. In most cases, the predominant, if not the only route of exposure will be dietary. Significant respiratory and dermal exposures will be unlikely.'' No comments were received on this statement during the first comment period for the proposal. The public was given the opportunity to comment on EPA's more detailed rationale supporting the statement. Fifth, EPA also described in greater detail how the rationale presented in the 1994 **Federal Register** document (59 FR at 60538, November 23, 1994) concerning the safety for human consumption of food containing residues of nucleic acids produced in plants as part of a plant-incorporated protectant applies to infants and children. The public was given the opportunity to comment on EPA's more detailed rationale addressing infants and children as part of the larger human population.

VI. What are the Key Features of the Final Rule?

In this final rule, EPA exempts residues of nucleic acids that are part of a plant-incorporated protectant. The following language is added to 40 CFR 174.475:

> Residues of nucleic acids that are part of a plant-incorporated protectant are exempt from the requirement of a tolerance.

Definitions at 40 CFR 174.3 relevant to the language at 40 CFR 174.475 include:

''Nucleic acids'' means 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.

Other definitions, relevant for plant-incorporated protectants only, can be found at 40 CFR 174.3 and are discussed in a companion document on FIFRA regulations published elsewhere in this issue of the **Federal Register**.

In this final rule, ''plant'' means an organism classified using the 5-kingdom classification system of Whittaker (Ref. 1) in the kingdom, Plantae. Therefore, the term ''plant'' includes, but is not limited to, bryophytes such as mosses, pteridophytes such as ferns, gymnosperms such as conifers, and angiosperms such as most major crop plants.

This exemption applies to the residues of genetic material necessary for the production of pesticidal substances in living plants, to residues of the genetic material necessary to produce any inert ingredient, to residues of nucleic acids used as the pesticidal substance (e.g., satellite RNA from plant viruses), and to residues of nucleic acids used in anti-sense technology. This exemption applies to naturally-occurring nucleic acids regardless of the sequence of the nucleic acid, the source of the sequence, or the function (e.g., template for a protein, or a regulatory element such as a promotor) the sequence encodes.

This final rule exempts only naturally-occurring nucleic acids, i.e., ribosides or deoxyribosides of adenine, guanine, cytosine, thymine, 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). It does not apply to nucleic acid analogues (e.g., didioxycytidine) or polymers containing nucleic acid analogues.

VII. How Do the Proposed Rule and Final Rule Differ?

This exemption from the requirement of a tolerance is adopted with a few changes from the proposed rule published in 1994 (59 FR 60545). EPA has changed the name of this type of pesticide from ''plant-pesticide'' to ''plant-incorporated protectant,'' as described in the companion document on FIFRA regulations for plant-incorporated protectants published elsewhere in this issue of the **Federal Register**.

Some modifications have been made to the text of the exemption and to associated definitions, for purposes of clarification. The definition of the term ''nucleic acids'' was modified to provide greater technical clarity; this modification does not change the scope of the exemption. These modifications are discussed in this document. A discussion of modifications to other relevant definitions, including an analysis of comments on those definitions, can be found in a companion document published elsewhere in this issue of the **Federal Register** on FIFRA regulations for plant-incorporated protectants.

When EPA proposed this exemption at 40 CFR 180.1138 from the requirement of a tolerance in 1994, it also stated its intention (59 FR at 60520) to establish a new 40 CFR part 174 specifically for plant-incorporated protectants. This new 40 CFR part 174 is being established in a companion document published elsewhere in this issue of the **Federal Register**. EPA adds this exemption from the requirement of a tolerance in § 174.475, subpart W, rather than adding it to 40 CFR part 180 as proposed.

VIII. Discussion of Final Rule and Public Comments

In this unit, EPA discusses the final rule and summarizes the comments it received on the November 23, 1994, proposed rule and subsequent supplemental documents. EPA reviewed and considered all comments received on the proposed rule and the supplemental documents and prepared detailed responses to these comments, which can be found at appropriate points in this preamble in its discussion of the final rule and the statutory finding.

In addition to being addressed in this preamble, comments are also addressed in the Agency's summary of public comments and EPA's response on issues associated with plant-incorporated protectants (Ref. 2).

A. From Whom Did EPA Receive Comment?

In response to the package of documents published in the **Federal Register** in 1994, EPA received letters from industry, academia, professional and trade associations, government agencies, state regulatory authorities, public interest groups and private citizens. Some of the commenters sent separate letters for each of the five dockets associated with the 1994 **Federal Register** documents. Other commenters sent a single letter addressing all five dockets. On July 22, 1996, EPA published a supplemental document seeking comment on the concept of inert ingredient with regard to plant-incorporated protectants. EPA received comments on this supplemental document. On May 16, 1997, EPA published a supplemental document to provide the public an

opportunity to comment on EPA's analysis of how certain amendments to FFDCA and FIFRA by the FQPA affected this proposed exemption. EPA received comments on the supplemental document. Copies of all comments received are available in the official record for this final rule as described in Unit X.

B. Exemption of Residues of Nucleic Acids that are Part of a Plant-Incorporated Protectant

On November 23, 1994 (59 FR 60542), EPA proposed to exempt from the FFDCA requirement of a tolerance, residues of nucleic acids (i.e., deoxyribonucleic acid and ribonucleic acid) produced in plants as part of a plant-incorporated protectant active or inert ingredient.

During the comment period for the 1994 proposal, EPA received 17 comments. Almost all of these comments supported the proposed exemption. Commenters agreed that nucleic acids are abundant in all plants and that humans have been and are routinely exposed to large amounts of nucleic acids as a normal part of their diet. One commenter stated that EPA's proposed exemption from the requirement of a tolerance for nucleic acids is consistent with the position of the Food and Drug Administration (FDA) with regard to nucleic acids.

In response to the July 22, 1996, supplemental document, EPA received 14 comments on the concept of inert ingredient with regard to plant-incorporated protectants. None of these comments addressed the issue of inert ingredient with regard to this exemption. (Comments on other aspects of the concept of inert ingredient are discussed in a companion document published elsewhere in this issue of the **Federal Register** on FIFRA regulations for plant-incorporated protectants).

In response to the May 16, 1997, supplemental document, EPA received four comments. All four comments supported the exemption. One of the four commenters indicated they knew of no information on substances, having cumulative effects or common mechanisms of toxicity with residues of nucleic acids, that would have a bearing on this exemption from the requirement of a tolerance. No comments were received on the other considerations raised by EPA in the supplemental document.

C. What is the Language of the Exemption?

No comments on the language of the proposed exemption were received. EPA modified the language of the proposed exemption and the proposed definition of nucleic acids, however, for greater clarity. In this unit, EPA discusses those changes. EPA also discusses what ''nucleic acids'' means in the context of this exemption, and how EPA's decision on inert ingredients for plant-incorporated protectants affects this exemption.

1. *What does the term ''nucleic acid'' mean?* Genetic material, including genetic material necessary for the production of the pesticidal substance, is composed of nucleic acids. Chemically, there are two types of nucleic acids: Deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) (Ref. 3). DNA is a polymer of purine and pyrimidine base deoxyribonucleoside monophosphates (also called deoxynucleotides) that are commonly referred to by the names of purine and pyrimidine bases: Adenine (A), cytosine (C), guanine (G), and thymine (T). A deoxynucleotide is made up of a sugar, a phosphate, and one of the four bases. In the DNA polymer, the sugars and phosphates of the deoxynucleotides are hooked together to form the ''backbone.'' One base is attached to each sugar in the sugar-phosphate backbone. RNA polymers are formed of similar linkages. RNA is a polymer of purine and pyrimidine base riboside monophosphates (also called nucleotides). The RNA nucleotides are also referred to by their base names: Adenine (A), cytosine (C), guanine (G), and uracil (U). In the RNA polymer, the sugar and phosphate moieties are also hooked together to form a backbone, with one base attached to each sugar moiety in the backbone. The information encoded in nucleic acids (either DNA or RNA) is determined by the sequence in which the bases are attached to the sugar-phosphate backbone (Ref. 3, 4). Nucleic acids encode all of the information necessary for the functioning of an organism. When a nucleic acid encoding a pesticidal substance is stably integrated into a plant, that plant and its progeny will, in most cases, have the potential to produce the pesticidal substance.

The ''nucleic acids'' of this exemption refer to the nucleic acids encoding the information for making polypeptides (proteins) which are the pesticidal substances or inert ingredients (e.g., selectable markers), or alternatively, encoding for proteins necessary for making (anabolizing) these substances. There may also be instances wherein nucleic acids may serve as the pesticidal substance. For example, satellite RNA of plant viruses may be used in strategies to control viral diseases in plants. In this situation, the RNA may be the pesticidal substance intended to control the pest. This exemption also applies to such RNA. This exemption for nucleic acids also applies to the DNA and RNA used in ''anti-sense'' technology, when this technology is used for pest resistance in plants. ''Anti-sense'' technology is used to block the production of a targeted enzyme or cellular component. In this technology, a segment of DNA encoding an RNA complementary (anti-sense) to the RNA necessary to produce the targeted enzyme or cellular component is introduced into the plant. For example, a company might wish to shut down an enzyme essential for pathogenesis by an agent that can cause disease in plants. To do so, the company would introduce into the genetic material of the plant, DNA encoding the anti-sense version of the RNA necessary to produce the targeted enzyme. The anti-sense version would bind to the normal version of the RNA necessary to produce the targeted enzyme. The normal (''sense'') version of the RNA would then no longer be available for processing in the cell, and, thus, the enzyme necessary for pathogenesis would not be produced. Because the essential enzyme cannot be produced, the disease-causing agent is not able to carry out one of the functions necessary for pathogenesis.

2. *What modifications were made to the language of the exemption?* In 1994, EPA proposed that residues of ''nucleic acids produced in living plants as part of a plant-pesticide active or inert ingredient, including both deoxyribonucleic and ribonucleic acids, are exempt from the requirement of a tolerance.'' In this final rule, EPA removes from the language of the exemption the phrase ''produced in living plants'' as this concept is part of the definition of plant-incorporated protectant. EPA was concerned that use of the phrase in the language of the exemption might cause some confusion because of this redundancy of concept. EPA also removed from the language of the proposed exemption, the phrase ''including both deoxyribonucleic and ribonucleic acids,'' also because of redundancy as the phrase appears in the definition of nucleic acids. Finally, EPA spelled out for greater technical clarity in the definition at 40 CFR 174.3 what substances are included in the concept of ''nucleic acids'' for plant-incorporated protectants, and what substances are excluded from the concept.

3. *How does the concept of inert ingredient relate to this exemption?* In the November 23, 1994, **Federal Register** document, EPA stated that an inert ingredient for plant-incorporated

protectants would be ''any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient'' (59 FR 60521). In a companion document published elsewhere in this issue of the **Federal Register**, EPA describes its consideration of inert ingredients in light of existing regulations and comments received in response to both the November 23, 1994, **Federal Register** document (59 FR 60534) and the 1996 supplemental document (61 FR 37891, July 22, 1996) discussing the Agency's treatment of selectable markers as inert ingredients for plant-incorporated protectants. In the companion document published elsewhere in this **Federal Register**, EPA describes its determination that it will apply the concept of inert ingredients to plant-incorporated protectants consistent with the 1994 proposal.

The preamble discussion in the 1994 **Federal Register** document (59 FR at 60544) of the rationale supporting the proposed rule to exempt residues of nucleic acids from the requirement of a tolerance addressed the nucleic acids necessary to produce any substance, such as a selectable marker, used to confirm or ensure the presence of the active ingredient. The exemption at 40 CFR 174.475 contains language indicating the exempt status of residues of the genetic material necessary for the production such substances.

IX. Statutory Finding

A. What Methodology Did EPA Use to Assess these Residues?

For most pesticides (e.g., chemical pesticides), EPA's dietary risk evaluation relies on data generated by testing in laboratories using representative animal models to estimate acute, subchronic, or chronic hazard end-points (e.g., acute toxicity, carcinogenicity, developmental toxicity). Conclusions from animal models are used to assess dose-response and describe such endpoints for potential human hazard. Other information, including residue data and information generated by use of mathematical models, are used to develop human exposure estimates. These exposure and hazard components are combined to quantify the potential risk associated with the pesticide's use. Uncertainty factors are often used in the risk assessment to account for extrapolation from animal models to human toxicity and from limited studies using humans to the larger population. The data requirements describing the types of information to be generated and other guidance for assessing dietary risk are detailed in 40 CFR part 158.

The questions posed as part of the risk assessment in evaluating residues of most pesticides (e.g., chemical pesticides) can also be posed for pesticide chemical residues that are the subject of this exemption, and 40 CFR part 158 can be used as guidance in evaluating these substances for hazard end-points (including, for example, acute toxicity, carcinogenicity, and developmental toxicity). To address the hazard endpoints described in 40 CFR part 158 for residues of nucleic acids that are part of a plant-incorporated protectant, EPA relied on a very large body of information found for the most part in the public scientific literature. A very large body of experience with actual human dietary consumption, over hundreds if not thousands of years, exists for the substances that are the subject of this exemption. And thus, a large and varied amount of information developed through systematic scientific study exists in the literature that can be used for assessing the risk of exempting nucleic acids. For example, there are numerous epidemiological studies on humans on foods containing nucleic acids (Refs. 5, 6, 7, 8, 9, 10, 11, 12, and 13), as well as a large literature on constituents of food from plants accumulated by a century of systematic study (Ref. 4).

EPA also considered other information in the literature in evaluating the potential for exposure to residues of nucleic acids that are part of a plant-incorporated protectant. Plant-incorporated protectants are produced within the living plant itself and the pesticidal substance is used *in situ* in a living plant to protect against pests, in contrast to most other pesticides which must be applied to the plant or the area around the plant (Ref. 14). Because a plant-incorporated protectant is produced and used within the plant, physiological constraints limit the amount of residue produced by the plant (Ref. 14). Because a plant-incorporated protectant is within the plant, routes by which other organisms may be exposed to the plant-incorporated protectant may be more limited; e.g., dietary exposure is likely to be the predominant route of exposure.

EPA relied on data in the area of plant genetics to provide information and knowledge on the genetic material that is necessary for the production of the pesticidal substances (Ref. 3). The Agency used experimental data derived from the science of phytopathology to characterize the disease and pest resistance mechanisms known to occur in plants (Ref. 15). EPA also considered information from the field of plant physiology regarding plant metabolism, particularly the metabolism of nucleic acids in plants (Refs. 3 and 17). EPA also used information from the fields of biochemistry, microbial ecology and ecology (Refs. 3, 15, 17, and 21).

For this exemption, EPA's risk assessment was based primarily on information in the publically available scientific literature as well as through experience with breeding and growing agricultural plants, and preparing and consuming food from such plants. Such food contains nucleic acids, as nucleic acids are ubiquitous in nature and in the food supply (Ref. 4). In exempting residues in food of nucleic acids that are part of a plant-incorporated protectant from the requirement of a tolerance, EPA considered health risks to the general population, including infants and children. Infants and children have always and currently consume food containing nucleic acids. There is no evidence that nucleic acids, as components of food, present a different level of dietary risk for infants and children than they would for the adult population. EPA's risk assessment also included subgroups as part of the general population, (i.e., differences in diet due to the influence of culture), and allowed for consumption pattern differences of such subgroups.

EPA believes human experience in consuming food containing nucleic acids combined with the numerous epidemiological and other studies and the knowledge of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry and plant breeding are the appropriate considerations in evaluating the potential risks of residues of nucleic acids that are part of a plant-incorporated protectant. All of these bases of knowledge and experience were integral to EPA's assessment of exposures and hazards associated with residues of nucleic acids that are part of a plant-incorporated protectant.

B. What Factors Has EPA Considered in Making the Findings Required by 408(c) of the FFDCA?

FFDCA section 408(c)(2)(B) requires EPA to consider several factors in determining whether to exempt a pesticide from the requirement of a tolerance. Information relevant to EPA's consideration of these factors with regard to this exemption is contained in this document, as well as in other

documents in the record for this final rule as described in Unit X.

1. *Validity, completeness and reliability of available data.* As noted in Unit IX.A., EPA's risk assessment was based primarily on an analysis of human experience with breeding and growing agricultural plants, and preparing and consuming food from such plants, and associated epidemiological studies, nutritional assessments with human volunteers and animal model testing (Refs. 5, 6, 7, 8, 9, 10, 11, 12, 13). EPA combined this information with knowledge from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry and plant breeding (Refs. 3, 15, 17, and 21, for example) to evaluate the potential risks of residues of nucleic acids that are part of a plant-incorporated protectant. EPA considered the validity, completeness and reliability of all available information. EPA concluded that this information was valid, complete and reliable, and adequately addressed the issues of hazard and exposure with regard to residues of nucleic acids in food.

2. *Nature of toxic effect.* EPA considered the nature of any toxic effects shown by this information to be caused by residues of nucleic acids that are part of a plant-incorporated protectant active or inert ingredient. Nucleic acids are widespread in foods (Ref. 4) and are not associated with toxic effects on animals or humans (Ref. 4, 18). Neither nucleic acids nor the substances of which nucleic acids are composed are known to be acute toxicants, but like proteins and other normal constituents of food, may cause indirect, adverse metabolic effects if consumed exclusively at high doses over a long period of time in the absence of a balanced diet. A person consuming food from plants containing residues of nucleic acids would not be consuming nucleic acids exclusively, and nucleic acids do not occur at these high doses in food plants. Consumption of nucleic acids in food has not been associated with any toxic effects (Ref. 18). Thus, because the residues of nucleic acids that are part of a plant-incorporated protectant are no different than other nucleic acids, including those that have been safely consumed, consumption of food containing residues of nucleic acids that are part of a plant-incorporated protectant are not expected to present a toxic effect. Simiarly, the nucleic acids in food from plants have not been associated with pathogenic effects on humans or other animals (Ref. 16), and residues in food of nucleic acids that are part of a plant-incorporated protectant are not expected to have pathogenic effects on humans or other animals.

3. *Relationship of studies to humans.* EPA considered the available information concerning the relationship of this information on nucleic acids in foods to human risk. The effect of nucleic acids on humans was assessed in light of the known presence of nucleic acids in all foods (Refs. 3 and 4) and the long history of human consumption of plant food containing nucleic acids, i.e., food derived from crop plants and from animals that consume forage and other crops containing nucleic acids. The epidemiological studies supply data generated on humans and thus are directly applicable to humans. Information from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry (including studies on the constituents of food) and plant breeding can be used to predict effects on humans. Nucleic acids in foods do not have a toxic effect and cause no adverse effects to humans. Because information on human consumption of food containing nucleic acids was available and adequately addressed the issues of hazard and exposure, EPA relied primarily on the epidemiological and other information generated directly from humans rather than relying on data generated in the laboratory through animal testing.

4. *Dietary consumption patterns.* EPA considered the available information on the varying dietary consumption patterns of consumers and major identifiable consumer subgroups as it pertains to residues of nucleic acids that are part of a plant-incorporated protectant in food. Issuance of this exemption from the requirement of a tolerance is not expected to alter the current consumption pattern of nucleic acids by consumers or major identifiable consumer subgroups. Nucleic acids are ubiquitous in all living organisms and in the food supply; thus, no subgroup is likely to receive a greater exposure nor a different exposure than any other subgroup.

5. *Available information concerning cumulative effects of the pesticide chemical residue and other substances that have a common mechanism of toxicity.* EPA has examined the available information as described in Unit IX.A. and Unit IX.B.1., on the cumulative effect of residues in food of nucleic acids that are part of a plant-incorporated protectant, and other substances that may have a common mechanism of toxicity. Nucleic acids are widespread in food (Ref. 4) and have not been associated with direct toxic effects to animals or humans (Ref. 18). Because nucleic acids in foods have no human toxicity, no cumulative effects can be identified for residues of nucleic acids that are part of a plant-incorporated protectant. The FQPA also directs the Agency to examine whether there are other substances that have a common mechanism of toxicity with nucleic acids that are part of a plant-incorporated protectant. Based on available information which indicates that nucleic acids in food have no human toxicity, EPA is not aware of any other substances that might have a common mechanism of human toxicity with residues of nucleic acids that are part of a plant-incorporated protectant.

The four comments EPA received on the May 16, 1997, supplemental document all supported the exemption. One of the four commenters indicated they knew of no information on substances, having cumulative effects or common mechanisms of toxicity with residues of nucleic acids, that would have a bearing on the exemption from the requirement of a tolerance.

EPA is not aware of any substances outside of the food supply that may have a common mechanism of toxicity with nucleic acids that are part of a plant-incorporated protectant since nucleic acids in food are not toxic. EPA has identified nucleic acid analogues (e.g., dideoxycytidine, zidovudine, dideoxyinosine) as substances having some level of toxicity (Ref. 19, 20). However, the mechanisms of toxicity of such analogues are not cumulative with that of residues of naturally-occurring nucleic acids.

6. *Aggregate exposure of consumers including non-occupational exposures.* EPA considered the available information on the aggregate exposure level of consumers to residues of nucleic acids that are part of a plant-incorporated protectant and to other related substances including nucleic acids that are not part of a plant-incorporated protectant. This included a consideration of exposures from dietary sources as well as from other non-occupational sources. Plant-incorporated protectants and their residues are likely to present a limited exposure to humans.

Nucleic acids produced in living plants are part of the metabolic cycles of plants. They are biotic and thus subject to the processes of biodegradation and decay that all biotic materials undergo (Ref. 21). Biotic materials are broken down to constituent parts through the enzymatic processes of living organisms, and these constituent parts used as the building

blocks to make other biotic substances. Because of these characteristics, the potential for exposures to the residues to occur, beyond direct physical exposure to the plant, is limited.

The residues that are the subject of this exemption are biodegradable to their constituent elements through catabolism by living organisms (Ref. 21). Because of their biodegradable nature, residues of nucleic acids do not bioaccumulate (bioaccumulation occurs when a substance is taken into the body through processes such as eating, and as the body is unable to either break the substance down or eliminate it, the substance accumulates in the tissues) or biomagnify in the tissues of living organisms (biomagnification occurs when a substance bioaccumulates in the bodies of organisms lower in the food chain, and as predators higher in the food chain consume organisms lower in the food chain, more and more of the substance accumulates in the bodies of organisms higher in the food chain). Humans ingesting the nucleic acids in food are likely to quickly degrade them and use their constituent elements as nutrients.

In most cases, the predominant exposure route will be dietary. 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. This is particularly true for residues of nucleic acids that are part of a plant-incorporated protectant, because large polymers are susceptible to rapid degradation. EPA expects non-dietary exposure (i.e., non-food oral, dermal and inhalation) in non-occupational settings to be negligible.

i. *Dietary exposure*. EPA considered dietary exposure to nucleic acids that are part of a plant-incorporated protectant. Nucleic acids are widespread in foods (Ref. 4), and all foods consumed by humans contain nucleic acids. As nucleic acids are ubiquitous in food, EPA concluded that all humans are exposed to nucleic acids throughout their lives as part of their diet. As described in Unit IX.A. and Unit IX.B.1., a large base of experience exists, including information on human dietary exposure, for foods that undoubtedly contain nucleic acids. Nucleic acids in food are not toxic and there is no evidence that consumption of nucleic acids in food leads to any harm.

ii. *Dermal exposure*. Residues of nucleic acids that are part of a plant-incorporated protectant may in some cases be present in sap or other exudates from the plant or the food, 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. However, on a per person basis, the potential amounts involved in these exposures are likely to be negligible in comparison to potential exposure through the dietary route. Moreover, nucleic acids as they occur in food are unlikely to cross the barrier provided by the skin (Refs. 22 and 23). This is particularly true for residues of nucleic acids that are part of a plant-incorporated protectant as these nucleic acids, for the most part, exist in the plant as polymers (Refs. 22 and 23).

iii. *Inhalation exposure*. Residues of nucleic acids that are part of a plant-incorporated protectant may be present in pollen, and some individuals (e.g., those near enough to farms, nurseries or other plant-growing areas to be exposed to wind-blown pollen, or visiting such areas) may be exposed, through inhalation, to the pollen. On a per person basis, the potential amounts of pollen involved in these exposures are likely to be negligible in comparison to potential exposure through the dietary route. It is unlikely that exposure to the pollen is equivalent to exposure to residues of nucleic acids that are part of a plant-incorporated protectant. In pollen, residues of nucleic acids will likely be integrated into the tissue of the pollen grain. Pollen grains are solid, insoluble particles of sufficiently large diameter that they are filtered out in the nasopharynx or in the upper respiratory tract (Refs. 23 and 24). Pollen grains containing residues that are the subject of this exemption are unlikely to cross the barrier provided by the mucous membrane of the respiratory tract (Refs. 23 and 24) and thus exposure through this route is not likely to be additive to dietary exposure of nucleic acids (Refs. 23 and 24).

iv. *Drinking water*. EPA also evaluated potential non-occupational exposures in drinking water. Residues of nucleic acids that are part of a plant-incorporated protectant are produced inside the plant itself. Nucleic acids, and residues of nucleic acids, are an integral part of the living tissue of the plant. 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 nucleic acids that are part of a plant-incorporated protectant) as building blocks for making their own cellular components or for fueling their own metabolisms (Ref. 21). Nucleic acids that are part of a plant-incorporated protectant are subject to the same processes of biodegradation and decay that all biotic materials undergo (Ref. 21) . This turnover of biotic materials in nature through a process of biodegradation occurs fairly rapidly. In addition, nucleic acids are, for the most part, highly unstable outside of the cellular environment and are usually very quickly broken down (Refs. 3 and 21). Because of the very rapid turnover of these residues, even if they reach surface waters (e.g., through plant parts falling into bodies of water), they are unlikely to present anything other than a very negligible exposure in drinking water drawn either from surface or ground water sources.

v. *Residential exposure*. EPA is not aware of any residential uses of plant-incorporated protectants that might result in exposure to residues of nucleic acids that are part of a plant-incorporated protectant.

7. *Sensitivities of subgroups*. EPA considered available information on the sensitivities of subgroups as it pertains to residues of nucleic acids that are part of a plant-incorporated protectant. As nucleic acids are ubiquitous in food, are not known to cause any adverse health effects when consumed in food and are not toxic, EPA does not expect that one subgroup would be more sensitive than another to residues of nucleic acids that are part of a plant-incorporated protectant.

8. *Estrogenic or other endocrine effects*. Based on available information concerning their structure and mode of action, plus the fact that nucleic acids are ubiquitous in foods and have no known adverse effects when consumed as part of the diet, EPA does not expect residues of nucleic acids that are part of a plant-incorporated protectant to cause estrogenic or other endocrine effects. No comment was received indicating that nucleic acids might have estrogenic or other endocrine effects in response to the specific request for such information in the May 16, 1997, supplemental document (62 FR 27142). If EPA becomes aware of a potential for estrogenic or endocrine effects from exposure to nucleic acids that are part of a plant-incorporated protectant, the Agency will reexamine this tolerance exemption in light of that information.

9. *Safety factors*. EPA did not rely solely on available animal data in reaching its determination that residues of nucleic acids that are part of a plant-incorporated protectant can be exempted from the requirement of a tolerance. There is a long history of safe human consumption of nucleic acids in

food derived from plants and from animals that consume forage and other crops (e.g., corn and other grains) containing nucleic acids. EPA thus was able to rely on epidemiological studies on humans (Refs. 5, 6, 7, 8, 9, 10, 11, 12, and 13) and a century of systematic scientific study of the constituents of food available in the public literature (Ref. 4). EPA also relied on knowledge in plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry and plant breeding. EPA believes that long-term evidence of human consumption and the associated information base (Refs. 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13), with a more limited reliance on animal experimentation data, are the appropriate information base for this exemption. Because the EPA was able to rely on data from humans, the Agency concluded that a safety factor designed to account for uncertainties in extrapolating from animal data would not be necessary. Because the available epidemiological and other information generated on humans was based on studies employing very large numbers of individuals, the Agency concluded that aten-fold safety factor to account for uncertainties in analyzing the human data would not be necessary.

10. *Infants and children*. EPA considered available information on consumption patterns of infants and children, including special sensitivity, cumulative effects of residues of nucleic acids that are part of a plant-incorporated protectant with other substances that may have a common mechanism of toxicity with these residues, and the need for a margin of safety for infants and children.

i. *Dietary consumption patterns*. EPA considered available information on the dietary consumption pattern of infants and children as it pertains to residues in food of nucleic acids that are part of a plant-incorporated protectant. 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 milk products for nutrition, although some infants are fed soy-based products. Infants begin as early as four months of age to consume specific types of solid foods. Subsequent to four months of age, apart from processing to facilitate swallowing, the diets of infants begin to be based on foods consumed by the general adult population albeit in different proportions. 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 changes to more closely resemble an adult diet. All foods consumed by infants and children, including milk and soy-based products, contain nucleic acids as do all foods consumed by adults. Since nucleic acids are ubiquitous in food, from the products infants consume after birth through the changing diets children consume as they mature, EPA concluded that infants and children have been, and are, exposed to nucleic acids as part of their diet. Although the diets of humans change from infancy through childhood and into adulthood, there is no evidence that such changes are likely to result in disproportionately high consumption of residues of nucleic acids, among infants and children in comparison to the general population. Nucleic acids in food are not toxic and there is no evidence that exposure to nucleic acids 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.

ii. *Special susceptibility*. EPA considered available information on the potential for special susceptibility of infants and children, including pre-natal and post-natal toxicity, to residues of nucleic acids that are part of a plant-incorporated protectant. Nucleic acids in food are not toxic and there is no scientific evidence that nucleic acids as a component of food would have a different effect on children, in light of neurological differences between infants and children and adults, than they would on the adult population.

iii. *Cumulative effects of residues with other substances with a common mechanism of toxicity*. EPA examined the available information on the cumulative effect of residues of nucleic acids that are part of a plant-incorporated protectant as well as other substances in food that may have a common mechanism of toxicity. The Agency's consideration of the effects of the residues of nucleic acids that are part of a plant-incorporated protectant on the general population also included consideration of effects on infants and children. Nucleic acids are not toxic when consumed as part of the diet, and EPA is not aware of substances that might have a common mechanism of toxicity with nucleic acids. There is no evidence indicating that adverse effects on infants and children due to aggregate exposure to residues of nucleic acids and other substances could occur.

iv. *Margin of safety*. In determining whether the residues of nucleic acids that are part of a plant-incorporated protectant are safe, FFDCA section 408(b)(2)(C) directs EPA to apply a tenfold margin of safety for the residues and other sources of exposure to infants and children to account for potential prenatal and postnatal toxicity and completeness of data on threshold effects with respect to exposure and toxicity to infants and children, unless a different margin will be safe. For residues of nucleic acids that are part of a plant-incorporated protectant, EPA has determined that a tenfold margin of safety is not necessary to protect infants and children. EPA reaches this determination based on reliable, valid and complete information. As noted in other sections of Unit IX., EPA based its assessment of exposure and toxicity upon the long history of safe human consumption of food containing nucleic acids from plants, and other animals that consume plants containing nucleic acids, and other substances in food that may have a common mechanism of toxicity (Ref. 4), and associated epidemiological and other studies (Refs. 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13). EPA also relied upon information from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry and plant breeding. Based on all of this information, EPA concludes that nucleic acids in food are not toxic and may be safely consumed, including by infants and children. There is no evidence that exposure to nucleic acids in food, including changes in exposure because of differences 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 nucleic acids in food are safe for infants and children, and that a margin of safety need not be applied for residues in food of nucleic acids that are part of a plant-incorporated protectant.

11. *Analytical methods*. EPA has decided that even though methodology exists to detect and measure the amount of nucleic acids in food and to detect and measure the residues of nucleic acids that are part of a plant-incorporated protectant (Ref. 4), there is no need to employ a practical method for detecting and measuring the levels of such residues. The effect of nucleic acids on humans was assessed in light of the known presence of nucleic acids in all foods (Refs. 3 and 4), the long history of safe human consumption of plant food containing nucleic acids, i.e., food derived from crop plants and from animals that consume forage and other crops containing nucleic acids, and associated epidemiological and other studies (Refs. 4, 5, 6, 7, 8, 9, 10, 11, 12,

and 13). EPA combined this information with knowledge from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry and plant breeding. Nucleic acids in foods do not have a toxic effect and cause no adverse effects to humans. There is no reason to believe that nucleic acids that are part of a plant-incorporated protectant would behave any differently than all of the other nucleic acids in food. There is a reasonable certainty that no harm will result from exposure to any amount of residues of nucleic acids that are part of a plant-incorporated protectant in food. 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 levels in food of the residues of nucleic acids that are part of a plant-incorporated protectant. EPA consulted with the Department of Health and Human Services (DHHS) in developing the proposed exemption and in issuing this final rule for residues of nucleic acids that are part of a plant-incorporated protectant.

C. Determination of Safety for United States Population, and Infants and Children

Based on the information discussed in this document and that discussed in the 1994 **Federal Register** documents and the supplemental documents and the record as described in Unit X., EPA concludes that there is a reasonable certainty that no harm will result to the United States population in general, and to infants and children in the United States, from aggregate exposure to residues of nucleic acids that are part of a plant-incorporated protectant, including all anticipated dietary exposures and all other exposures for which there is reliable information. Under this exemption from the requirement for a tolerance, EPA exempts residues of nucleic acids that are part of a plant-incorporated protectant. Nucleic acids are normally a component of food from plants. Extensive use and experience show the safety of foods containing nucleic acids. The many years of human experience with the growing, preparing and consuming food from plants containing nucleic acids and information generated through years of study of the food supply (Refs. 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13), indicate that adverse effects due to aggregate exposure through the dietary, non-food oral, dermal and inhalation routes are highly unlikely.

X. Documents in the Official Record

As indicated in Unit I.B.2., the official record for this final rule has been established under docket control number OPP–300371B, the public version of which is available for inspection as specified in Unit I.B.2.

A. References

The following books, articles and reports were used in preparing this final rule and were cited in this document by the number indicated:

1. Whittaker, R. H. 1969. New concepts of kingdoms of organisms. Science, 163:150–160.

2. Environmental Protection Agency (EPA). 2000. Summary of public comments and EPA response on issues associated with plant-incorporated protectants (formerly plant-pesticides) for dockets OPP–300371 and OPP–300371A.

3. Goodwin, T. W. and E. I. Mercer. 1983. Introduction to Plant Biochemistry. Pergamon Press. Oxford, New York, Toronto, Sydney, Paris, Frankfurt.

4. International Food Biotechnology Council. 1990. Biotechnologies and food; Assuring the safety of foods produced by genetic modification. In: Regulatory Toxicology and Pharmacology. Volume 12. Academic Press, Inc. New York, New York.

5. World Cancer Research Fund and American Institute for Cancer Research. 1997. Food, Nutrition and the Prevention of Cancer: A Global Perspective. BANTA Book Group, Menasha, Wisconsin.

6. Lampe, J. M. 1999. Health effects of vegetables and fruit: assessing mechanisms of action in human experimental studies. *American Journal of Clinical Nutrition*. Sep;70(3 Suppl):475S–490S.

7. Ogomoto, I. A. Shibata and K. Fukuda. 2000. World Cancer Research Fund/American Institute of Cancer Research 1997 recommendation: applicability to digestive tract cancer in Japan. Cancer Causes Control Jan;11(1):9–23.

8. Joseph, J. A., B. Shukitt-Hale, N. A. Denisova, D. Bielinski, A. Martin, J. J. McEwen and P. C. Bickford. 1999. Reversals of age-related declines in neuronal signal transduction, cognitive, and motor behavioral deficits with blueberry, spinach, or strawberry dietary supplementation. *Journal of Neuroscience*. Sep 15;19(18):8114–21.

9. Segasothy, M. And P. A. Phillips. 1999. Vegetarian diet: panacea for modern lifestyle diseases? *QJM Monthly Journal of the Association of Physicians* Sep;92(9):531–44.

10. Joshipura, K. J., A. Ascherio, J. E. Manson, M. J. Stampfer, E. B. Rimm, F. E. Speizer, C. H. Hennekens, D. Spiegelman and W. C. Willett. 1999. Fruit and vegetable intake in relation to risk of ischemic stroke. *Journal of the American Medical Association*. Oct6;282(13)1233a–9.

11. Thompson, H. J., J. Heimendinger, A. Haegele, S. M. Sedlacek, C. Gillette, C. O'Neill, P. Wolfe and C. Conry. 1999. Effect of increased vegetable and fruit consumption on markers of oxidative cellular damage. *Carcinogenesis* Dec;20(12):2261–6.

12. New, S. A., S. P. Robins, M. K. Campbell, J. C. Martin, M. J. Garton, C. Boltin-Smith, D. A. Grubb, S. J. Lee and D. M. Reid. 2000. Dietary influences on bone mass and bone metabolism: further evidence of a positive link between fruit and vegetable consumption and bone health? *American Journal of Clinical Nutrition*. Jan;71(1):142–51.

13. Michaud, D. S., D. Spiegelman, S. K. Clinton, E. B. Rimm, W. C. Willett and E. L. Giovannucci. 1999. Fruit and vegetable intake and incidence of bladder cancer in a male prospective cohort. *Journal of the National Cancer Institute*. Apr7;91(7):605–13.

14. EPA issue paper. 1994. FIFRA: Benefit and environmental risk considerations for inherent plant-pesticides.

15. Agrios, George. 1988. Plant Pathology. Third Edition. Academic Press. New York, New York.

16. Principles and Practice of Infectious Diseases. 1979. Edited by G. L. Mandell, R. G. Douglas, Jr. and J. E. Bennett. John Wiley and Sons, New York.

17. Raven, P. H., R. F. Evert, and S. E. Eichhorn. 1992. Biology of Plants. Fifth Edition. Worth Publishers, New York, New York.

18. Environmental Protection Agency (EPA). Meeting of the EPA Biotechnology Science Advisory Committee (BSAC); Subcommittee on plant-pesticides. July 13, 1993. Final Report.

19. Hayden, F. G. 1996. Antiviral agents. In: Goodman and Gilmans's The Pharmacological Basis of Therapeutics. Ninth Edition. Edited by J. G. Hardman, L. E. Limbird, P. B. Molinoff, and R. W. Rudden. McGraw-Hill Health Profession Division. New York, New York.

20. Ellenhorn's Medical Toxicology: Diagnosis and Treatment of Human Poisoning. 1997. Second Edition. M. J. Ellenhorn, S. Schonwald, G. Ordog, J. Wasserberger. Williams and Wilkins. Baltimore, Maryland.

21. Atlas, R. and R. Bartha. 1987. Microbial Ecology. Benjamin/Cummings

Publishing Company, Inc. Menlo Park, California.

22. Guy, R. H., and J. Hadgraft. 1991. Principles of skin permeability relevant to chemical exposure. In: Dermal and Ocular Toxicology: Fundamentals and Methods. Edited by D. W. Hobson. CRC Press Boca Raton, Florida.

23. Environmental Protection Agency (EPA) issue paper. 2000. Dermal and inhalation exposure to plant substances.

24. Environmental Protection Agency. 1997. Exposure Factors Handbook. Volume 1. National Center for Environmental Assessment. EPA/600/P-95/002Fa.

25. Environmental Protection Agency (EPA). 2000. Economic analysis of the plant-incorporated protectant regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

B. Additional Information

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 Protein 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–30069A 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–300368B for the companion 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)'' (FRL–6057–6) published elsewhere in this issue of the **Federal Register**.

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)'' (FRL–6057–7) published elsewhere in this issue of the **Federal Register**, and the docket identified by the docket control number OPP–300370B for the document entitled ''Plant-Incorporated Protectants; Supplemental Notice of Availability of Information'' (FRL–6760–4).

Also included in the complete official public 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 Science Advisory Panel pertaining to the development of this final rule.

3. The Economic Analysis (EA) on FIFRA regulations for plant-incorporated protectants, and documents supporting the EA (Ref. 25).

4. Support documents and reports.

5. Records of all communications between EPA personnel and persons outside EPA pertaining to the final rule. (This does not include any inter-agency and intra-agency memoranda, unless specifically noted in the Indices of the dockets).

6. Published literature that is cited in this document.

7. The response to comments document pertaining to the development of this final rule (Ref. 2).

XI. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408 and does not impose any other regulatory requirements. As such, the Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

This action does not 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), nor does it 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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

This action does not impose any enforceable duty or contain any unfunded mandate, and will not otherwise significantly or uniquely affect small governments as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).This rule does not significantly or uniquely affect the communities of Indian trial governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084, entitled *Consultation and Coordination with*

Indian Tribal Governments (63 FR 27655, May 19, 1998), do not apply to this rule. Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), which took effect on January 6, 2001, revokes Executive Order 13084 as of that date. EPA developed this rulemaking, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13084. For the same reasons stated for Executive Order 13084, the requirements of Executive Order 13175 do not apply to this rule either. For the same reasons, this rule does not have any substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). This rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The Agency's determination is based on the fact that an exemption from the requirement of a tolerance under FFDCA section 408, such as that contained in this rule, will not adversely affect any small businesses. Additional information about the Agency's determination may be found in the small entity impact analysis prepared as part of the economic analysis for the FIFRA rulemaking, which is available in the public version of the official record (Ref. 25). The Agency has also 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 these actions. See 46 FR 24950, May 4, 1981.

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 this action is not expected to affect energy supply, distribution, or use.

XII. Submission to Congress and the Comptroller General

The Congressional Review Act, 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. 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 this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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: July 12, 2001.

Christine T. Whitman,

Administrator.

Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y and 21 U.S.C. 346a and 371.

2. Section 174.475 is added to subpart W to read as follows:

§ 174.475 Nucleic acids that are part of a plant-incorporated protectant; exemption from the requirement of a tolerance.

Residues of nucleic acids that are part of a plant-incorporated protectant are exempt from the requirement of a tolerance.

[FR Doc. 01–17982 Filed 7–16–01; 11:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[OPP–300368B; FRL–6057–6]

RIN 2070–AC02

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)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The substances plants produce for protection against pests, and the genetic material necessary to produce these substances, are pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if humans intend to use these substances for ''preventing, destroying, repelling or mitigating any pest.'' These substances, produced and used in living plants, along with the genetic material necessary to produce them, are also ''pesticide chemical residues'' under the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA calls these substances, along with the genetic material necessary to produce them, plant-incorporated protectants. In this final rule, EPA exempts from the FFDCA section 408 requirement of a tolerance, residues of the pesticidal substance portion and residues of any inert ingredient of any plant-incorporated protectant derived through conventional breeding from a plant sexually compatible with the recipient food plant. EPA has determined that there is a reasonable certainty that no harm will result from aggregate exposure to these residues.

DATES: This rule is effective September 17, 2001. Objections and requests for hearings must be received by EPA on or before September 17, 2001.

ADDRESSES: Objections and hearing requests may be submitted by regular mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit II. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: By mail: Philip Hutton, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington DC 20460; telephone number: (703)

308–8260; e-mail address: hutton.phil@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 plant-incorporated protectants. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Pesticide manufacturers	32532	Establishments primarily engaged in the formulation and preparation of agricultural and household pest control chemicals
Seed companies	111	Establishments primarily engaged in growing crops, plants, vines, or trees and their seeds
Colleges, universities, and professional schools	611310	Establishments of higher learning which are engaged in development and marketing of plant-incorporated protectants
Establishments involved in research and development in the life sciences	54171	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 above could also be affected. The North American Industrial Classification System (NAIC) 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 part 174 in title 40 of the Code of Federal Regulations (CFR). If you should have any questions regarding the applicability of this action to a particular entity, consult the technical person listed in the **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information , Including Copies of This Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. To access information about the EPA's program for biopesticides go directly to the Home Page for the Office of Pesticide Programs at http://www.epa.gov/pesticides/biopesticides.

2. *In person.* The Agency has established an official record for this action under the docket control number OPP–300368B. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Record Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

II. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the Food Quality Protection Act (FQPA), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA,

you must identify docket control number OPP–300368B in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 17, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public version of the official record without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit II., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–300368B, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

III. Under What Authority Is EPA Issuing this Final Rule?

This exemption from the requirement of a tolerance is being issued under the authority of section 408(c) of the FFDCA (21 U.S.C. 346a(c)). 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 other 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 the 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 a commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical'' (21 U.S.C. 321(q)(2)). The 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)). 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'' with certain exceptions (7 U.S.C. 136(t)).

Under FFDCA section 408(c), EPA can establish an exemption from the requirement of a tolerance for a ''pesticide chemical residue'' only if EPA determines that granting such an exemption is ''safe'' (21 U.S.C. 346a(c)(2)(A)(i)). The 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'' (21 U.S.C. 346a(c)(2)(A)(ii)). This includes exposure through drinking water, and residential and other indoor uses, but does not include occupational exposure. In establishing an exemption from the requirement of a tolerance, FFDCA section 408(c) does not authorize EPA to consider potential benefits associated with use of the pesticide chemical in determining whether the pesticide chemical may be exempted.

FFDCA section 408 requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption 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'' (21 U.S.C. 346a(b)(2)(C)(ii)(I)) and (c)(2)(B)). FFDCA section 408(b)(2)(D) specifies other general factors EPA must consider in establishing an exemption (21 U.S.C. 346a(b)(2)(D)). FFDCA section 408(c)(3) prohibits an exemption unless there is either a practical method for detecting and measuring levels of pesticide chemical residue in or on food or there is no need for such a method, requiring EPA to state the reason for this determination (21 U.S.C. 346a(c)(3)).

IV. Context

A. What Role Does this Exemption Play in EPA's Approach to Plant-Incorporated Protectants?

The substances plants produce for protection against pests are pesticides under the FIFRA definition of pesticide, if humans intend to use these substances for ''preventing, destroying, repelling or mitigating any pest.'' These substances, produced and used in living plants, along with the genetic material necessary to produce them, are designated ''plant-incorporated protectants'' by EPA.

To understand the role this exemption plays in EPA's approach to plant-incorporated protectants, the following two considerations must be understood. First, what constitutes the residues of plant-incorporated protectants derived through conventional breeding from plants sexually compatible with the recipient plant and why EPA is exempting them from the requirement of a tolerance. Second, how this exemption from the FFDCA requirement of a tolerance for residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants relates to the exemption from the FFDCA requirement of a tolerance published elsewhere in this issue of the **Federal Register** for residues of nucleic acids that are part of a plant-incorporated protectant.

1. *What constitutes the residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants and why is EPA exempting them?* In developing its approach to plant-incorporated protectants, EPA took into account the properties of pesticidal and other substances produced and used in plants. In particular, EPA recognized that plants have evolved, and thus naturally possess, various mechanisms to resist pests. The mechanisms of resistance can be varied, including, for example, structural characteristics of the plant, the production of general metabolites that have toxic properties, or the production of specific toxic substances in response to pest attack. In breeding plant varieties, humans have frequently intentionally used these mechanisms to create varieties with varying abilities to prevent, destroy, repel or mitigate pests. Based on human experience in breeding, growing, preparing, and consuming food from such plant varieties and the large and varied information developed through systematic scientific study available in the literature, EPA recognized that residues of many plant-incorporated protectants, in or on food or feed, would qualify for exemption from regulation under FFDCA section 408. (Hereafter, EPA will use the term ''in food'' to represent the concept of ''in or on food or feed'' in this preamble).

For EPA to exempt any residue of a pesticide, including any residue of a plant-incorporated protectant, EPA must find that there is a reasonable certainty that no harm will result from aggregate exposure to the residue, including all anticipated dietary exposures and all other exposures for which there is reliable information. EPA takes this action today with regard to residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants because it has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the residues, including all anticipated dietary exposures and all other exposures for which there is reliable information.

Under FFDCA section 408, the term residue is defined broadly to include residues of the active and inert ingredients of the pesticide itself and residues that are present in the food as a result of the metabolism or other degradation of the pesticide (21 U.S.C. 321(q)). For plant-incorporated protectants derived through conventional breeding from sexually compatible plants, EPA anticipates the residues will consist of the pesticidal substance and the genetic material necessary for production of the pesticidal substance, and any substance that might function as an inert ingredient as defined for plant-incorporated protectants (e.g., any selectable marker), and the genetic material necessary for production of the inert ingredient.

This action exempts from the requirement of a tolerance under FFDCA section 408, residues of the pesticidal substance portion of plant-incorporated protectants derived through conventional breeding from plants sexually compatible with the recipient plant, and residues of any inert ingredient introduced through conventional breeding from plants sexually compatible with the recipient plant. For plant-incorporated protectants, the recipient plant is the living plant that receives the genetic material necessary to produce the pesticidal substance and in which the plant-incorporated protectant is intended to be produced and used.

2. *How does this exemption relate to the exemption from the FFDCA requirement of a tolerance for residues of nucleic acids?* This exemption can be paired with EPA's tolerance exemption for residues of nucleic acids that are part of a plant-incorporated protectant, published elsewhere in a companion document in this issue of the **Federal Register**. That exemption applies to residues of the genetic material portion of all plant-incorporated protectants, and, thus, also applies to residues of the genetic material necessary for the production of the pesticidal substance portion of plant-incorporated protectants derived through conventional breeding from sexually compatible plants, and the residues of the genetic material necessary for the production of any inert ingredient introduced through conventional breeding from plants sexually compatible with the recipient plant. Because of these actions, all residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants are exempt from FFDCA section 408 requirements.

B. Does this Final Rule Have Any Relevance to Other Types of Pesticides?

Nonviable plant tissues, organs or parts that are used as pesticides, will not be covered by this exemption. Residues of such pesticides are subject to the regulations found in 40 CFR parts 177 through 180 rather than 40 CFR part 174. An example of this type of pesticide would be the powder, produced by drying and grinding cayenne pepper, dusted on plants to protect them from pests.

Residues of substances that are isolated from a plant's tissues and then applied to plants and/or to food for pest control will not be covered by this exemption. Residues of these types of pesticides in formulations such as those for foliar application are subject to regulations found in 40 CFR parts 177 through 180 rather than 40 CFR part 174. An example of this type of pesticide would be pyrethrum isolated from chrysanthemum plants, formulated with other ingredients for foliar application, and sprayed onto other plants for pest control.

Residues of substances that are synthesized will not be covered by this exemption. Residues of such pesticides are subject to regulations found in 40 CFR parts 177 through 180 rather than 40 CFR part 174. An example of this type of pesticide is the herbicide, atrazine.

C. What Is the History of this Final Rule?

This final rule is an additional step in fully implementing the ''Coordinated Framework for Regulation of Biotechnology'' of the United States of America which was published in the **Federal Register** by the Office of Science and Technology Policy (OSTP) on June 26, 1986 (51 FR 23302).

EPA sponsored, or co-sponsored with other Federal agencies, three conferences dealing with plant related issues: On October 19–21, 1987, a meeting on''Genetically Engineered Plants: Regulatory Considerations'' at Cornell University, 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. Information from these conferences has been incorporated as appropriate in development of this final rule.

In developing its approach to plant-incorporated protectants, EPA requested the advice of two scientific advisory groups at three meetings. On December 18, 1992, pursuant to section 25 of FIFRA, a subpanel of the FIFRA Scientific Advisory Panel (SAP) was convened to review a draft policy on plant-pesticides (now called plant-incorporated protectants) and to respond to a series of questions posed by the Agency, primarily on 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 plant-pesticides under FFDCA. On January 21, 1994, a joint meeting of the subpanel of the SAP and the BSAC subcommittee was held and EPA asked advice on approaches to plant-pesticides under both FIFRA and FFDCA. Advice from these scientific advisory groups was considered in finalizing this rule.

EPA published in the November 23, 1994, **Federal Register** a package of five separate documents (59 FR 60496, 60519, 60535, 60542, 60545) (FRL–4755–2, FRL–4755–3, FRL–4755–4, FRL–4755–5, FRL–4755–8) which described EPA's policy and proposals for plant-pesticides under FIFRA and FFDCA. Included in that package was a proposal to exempt from the FFDCA requirement of a tolerance, residues of the pesticidal substance portion of plant-pesticides derived from closely related plants.

On July 22, 1996, EPA published a supplemental document in the **Federal Register** (61 FR 27891) (FRL–5387–4) on one aspect of its November 23, 1994, **Federal Register** documents; i.e., how the concept of inert ingredient related to plant-pesticides.

In August of 1996, Congress enacted the FQPA which amended the FFDCA and FIFRA. On May 16, 1997, EPA published in the **Federal Register** a supplemental document (62 FR 27132) (FRL–5717–2) to provide the public with an opportunity to comment on EPA's analysis of how certain FQPA amendments to the FFDCA and FIFRA apply to the proposed tolerance exemption for pesticide chemical residues derived from closely related plants.

On April 23, 1999, EPA published a supplemental document (64 FR 19958) (FRL–6077–6) in the **Federal Register** soliciting comment on whether to change the name of this type of pesticide.

The documents and the reports of the meetings described above are available in the record for the rulemaking for plant-incorporated protectants as described in Unit X.

V. What are the Key Features of the Proposed Exemption?

The development of this exemption consists of a proposed rule which appeared in the November 23, 1994, **Federal Register** (59 FR 60535), and two supplemental documents; one document that appeared on July 22, 1996, in the **Federal Register** (61 FR 37891), and a second that appeared in the May 16, 1997, **Federal Register** (62 FR 27132).

A. November 23, 1994, **Federal Register** *Proposed Rule*

In the 1994 **Federal Register** document (59 FR 60535, November 23, 1994), EPA proposed to exempt residues of a category of plant-pesticides it believed would qualify for an exemption. The proposed exemption was based upon the premise that new dietary exposures would not likely arise for these residues if the genetic material leading to the production of the pesticide chemical residues is derived from a plant that is closely related to the recipient plant; i.e., if the plant that is the donor of the genetic material is closely related to the plant receiving the genetic material.

In the 1994 **Federal Register** document, EPA presented two options for describing a standard based on the relatedness of plants. Option 1, the Agency's preferred option proposed at 40 CFR 180.1137(a), used sexual compatibility as a measure of relatedness between plants. Under this option, residues of a pesticidal substance produced in a living plant as part of a plant-pesticide would be exempt from the requirement of a tolerance if the genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is derived from a plant that is sexually compatible with the recipient plant and has never been derived from a source that is not sexually compatible with the recipient plant.

Option 2 would utilize the rank of genus as the taxonomic standard for describing closely related plants, as well as sexual compatibility. This option would exempt residues of a pesticidal substance derived from a plant classified in the same genus as the recipient plant, as well as residues of a pesticidal substance derived from a plant sexually compatible with the recipient plant. Under both Options 1 and 2, residues of the pesticidal substance derived from plants sexually compatible with the recipient plant would be exempt, even if the source and recipient plants are classified in different genera.

EPA proposed that ''sexually compatible,'' when referring to plants, would mean ''capable of forming a viable zygote through the fusion of two gametes, including the use of bridging and/or wide crosses between plants.'' EPA proposed that ''bridging crosses between plants'' would mean the ''utilization of an intermediate plant in a cross between the intermediate plant and the first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of the first and third plant through the formation of an intermediate zygote.'' EPA proposed that ''wide crosses between plants'' would mean ''to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppression, *in vitro* fertilization, pre-pollination and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures or any other technique that the Administrator determines meets this definition.''

Neither of the options was intended to exempt residues of a pesticidal substance that is significantly different functionally from the pesticidal substance as it occurs in the source plant.

The Agency also requested comment on the utility of an exemption criterion based on the process (e.g., rDNA) used to introduce the plant-incorporated protectant into a plant (59 FR at 60514, 60540, 60541). This approach was discussed by the SAP Subpanel and BSAC Subcommittee at the joint meeting of these scientific advisory groups held on January 21, 1994. In this approach, residues of plant-incorporated protectants developed through techniques other than those of modern biotechnology would be exempted, e.g., residues of those plant-incorporated protectants developed through conventional plant breeding would be exempted. Residues of those plant-incorporated protectants that were not exempted could subsequently be considered for exemption on the basis of risk potential.

The joint Subcommittee/Subpanel report justified such an approach on the following three considerations. First, the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules established a precedent that has worked well. Second, although new techniques, such as rDNA are more precise than conventional plant breeding, it is possible to make with rDNA novel genetic modifications never before possible. The novel combinations possible with modern genetic techniques create uncertainties about how the gene will function and how its products may affect the plant's phenotype and its impact upon the environment and human health. Third, establishing rDNA methodologies as a criterion for oversight may give the public more confidence that risk potential is being evaluated. As a result, approved products may move to the marketplace more easily (Ref. 6).

B. What Issues Were Discussed in the Supplemental Documents?

Subsequent to publication of the November 23, 1994 **Federal Register** document (59 FR 60535), EPA published two supplemental documents directly relevant to this exemption: one on July 22, 1996 (61 FR 37891), and another on May 16, 1997 (62 FR 27132).

1. *July 22, 1996.* The July 22, 1996, supplemental document (61 FR 37891) discussed how the concept of inert ingredient related to plant-pesticides.

2. *May 16, 1997.* In August of 1996, the FFDCA and FIFRA were amended by the FQPA. On May 16, 1997, EPA published in the **Federal Register**, a supplemental document (62 FR 27132) to provide the public with an opportunity to comment on EPA's analysis of how certain FQPA amendments to the FFDCA and FIFRA affect this proposed exemption.

EPA stated in the May 16, 1997, supplemental document its belief that most of the substantive factors the FFDCA now requires EPA to consider when evaluating pesticide residues were considered when the Agency proposed the exemption in 1994. EPA, thus, in the supplemental document, specifically sought comment only on its evaluation of the requirements imposed by FQPA that the Agency had not addressed in the proposed rule. EPA sought comment on the following five considerations. First, whether there are substances, outside of the food supply, sharing a common mechanism of toxicity with residues of pesticidal substances derived from sexually compatible plants. Commenters were asked to submit information on the cumulative effects of such substances and the pesticidal substances that were the subject of the proposed exemption (59 FR 60535). Second, whether there are substances, outside of the food supply, related via a common mechanism of toxicity to such residues to which humans might be exposed through non-occupational routes of exposure. Commenters were asked to describe routes through which such exposure might occur, including exposure to major identifiable subgroups of human populations (e.g., infants and children). Commenters were requested, if such routes were identified, to provide information on the nature and levels of expected exposures. Comments were also sought on these two issues with regard to Option 2, the alternative option for describing closely related plants (described in Unit V.A.). Third, commenters who possess information on substances occurring in food from plants that may have estrogenic effects and may be used as plant-incorporated protectants were requested to send such information to EPA. Fourth, EPA described in greater detail the rationale supporting the statement made in the 1994 **Federal Register** document (59 FR at 60513) that ''plant-pesticides are likely to present a limited exposure of pesticidal substances to humans. In most cases, the predominant, if not the only, route of exposure will be dietary. Significant respiratory and dermal exposures will be unlikely.'' No comments were received on this statement during the first comment period for the proposed rule. The public was given the opportunity to comment on EPA's more detailed rationale supporting the statement. Fifth, EPA also described in greater detail how the rationale presented in the 1994 **Federal Register** document (59 FR at 60538) concerning the safety for human consumption of food from plants that meet the sexually compatible standard applies to infants and children. The public was given the opportunity to comment on the more detailed rationale specifically addressing infants and children as part of the larger human population.

VI. What are the Key Features of this Final Rule?

In this final rule, EPA exempts residues of the pesticidal substance and inert ingredient portion of plant-incorporated protectants derived through conventional breeding from plants sexually compatible with the recipient plant. The following language is added to 40 CFR 174.479:

> Residues of a pesticidal substance that is part of a plant-incorporated protectant from a sexually compatible plant are exempt from the requirement of a tolerance if all the following conditions are met:
>
> (a) The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient food plant.
>
> (b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.
>
> (c) The residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health.

Pertinent associated definitions in 40 CFR 174.3 are discussed in greater detail in a companion document published elsewhere in this issue of the **Federal Register** on FIFRA regulations for plant-incorporated protectants.

In this final rule, plant means an organism classified using the 5-kingdom classification system of Whittaker (Ref. 1) in the kingdom, Plantae. Therefore, the term ''plant'' includes, but is not limited to, bryophytes such as mosses, pteridophytes such as ferns, gymnosperms such as conifers, and angiosperms such as most major crop plants.

Also included in the regulatory text at § 174.485, subpart X, is an exemption for residues of inert ingredients in plants derived through conventional breeding from sexually compatible plants.

VII. How Do the Proposed Rule and Final Rule Differ?

This exemption from the requirement of a tolerance is adopted with several

changes from the proposed rule published in 1994 (59 FR 60535, November 23, 1994). EPA has changed the name of this type of pesticide from ''plant-pesticide'' to ''plant-incorporated protectant'' as described in the companion document on FIFRA regulations for plant-incorporated protectants published elsewhere in this issue of the **Federal Register**. EPA exempts at this time only a subgroup of the category it proposed to exempt in 1994: Residues of pesticidal substances and inert ingredients derived through conventional breeding from plants sexually compatible with the recipient plant. In a companion document published elsewhere in this issue of the **Federal Register**, EPA solicits additional comment on alternative options for the plant-incorporated protectants derived through modern biotechnology, e.g., recombinant DNA techniques, from plants sexually compatible with the recipient plant.

In response to concerns expressed in comments and to make EPA's approach more consistent with the policy of the Food and Drug Administration (FDA), EPA has added a condition to the exemption that addresses levels of substances that are injurious or deleterious to human health in food from plants in sexually compatible populations. A few other modifications have been made to the text of the exemptions, for purposes of clarification. A discussion of modifications to other relevant definitions, including an analysis of comments on those definitions, can be found in a companion document published elsewhere in this issue of the **Federal Register** on FIFRA regulations for plant-incorporated protectants. Discussion of all modifications can be found in the documents summarizing public comments and EPA responses on issues associated with plant-incorporated protectants (Ref. 2) located in the record for this rule as described in Unit X.

When EPA proposed the exemption in 1994 at 40 CFR 180.1137(a), it also stated its intention (59 FR at 60520) to establish a new 40 CFR part 174 specifically for plant-incorporated. This new 40 CFR part 174 is being established in a companion document published elsewhere in this issue of the **Federal Register**. EPA adds this tolerance exemption to 40 CFR 174.479, subpart W, rather than adding it to 40 CFR part 180 as proposed.

VIII. Discussion of Final Rule and Public Comments

In this unit, EPA discusses the final rule and summarizes the comments it received on the November 23, 1994 proposed rule and the May 16, 1997 supplemental document. EPA reviewed and considered all comments received on the proposed rule and supplemental document and prepared detailed responses to these comments. These responses can be found at appropriate points in this preamble and in the Agency's summary of public comments and EPA's response on issues associated with plant-incorporated protectants (Ref. 2).

A. From Whom Did EPA Receive Comments?

In response to the package of documents published in the **Federal Register** in 1994, EPA received letters from industry, academia, professional and trade associations, government agencies, state regulatory authorities, public interest groups and private citizens. Some of the commenters sent separate letters for each of the five dockets associated with the 1994 **Federal Register** documents. Other commenters sent a single letter addressing all five dockets. EPA received comments on the July 22, 1996, supplemental document, and on the May 16, 1997, supplemental document, which provided the public an opportunity to comment on EPA's analysis of how certain amendments to the FFDCA and FIFRA by FQPA affected this proposed exemption. Copies of all comments received are available in the record for this rule as described in Unit X.

B. Exemption of Residues of Plant-Incorporated Protectants Derived Through Conventional Breeding from Sexually Compatible Plants

On November 23, 1994 (59 FR 60535), EPA proposed to exempt from the FFDCA requirement of a tolerance, all residues of a category of plant-incorporated protectants based on the premise that new dietary exposures would be unlikely if the genetic material leading to the production of the plant-incorporated protectant is derived from a plant closely related to the recipient plant. EPA offered two options for defining plant-incorporated protectants derived from plants closely related to the recipient plant. The options were somewhat different approaches to describing a high degree of relatedness between the genetic donor and the recipient plant. Neither of the options was based on the process by which a plant-incorporated protectant was introduced into the recipient plant. Option 1, based upon sexual compatibility, was EPA's preferred option (59 FR 60542). Option 2, used taxonomy (genus) in conjunction with sexual compatibility to define closely related plants. The Agency also requested comment on the utility of an exemption criterion based on the process (e.g., rDNA) used to introduce the plant-incorporated protectant into a plant (59 at FR 60514, 60540, 60541).

During the comment period for the 1994 proposed rule, EPA received 19 comments addressing the options for describing pesticidal substances derived from closely related plants. Nine of these comments supported Option 1 and generally agreed that the sexual compatibility standard is reasonable and adequately addresses food safety issues. Three comments favored Option 2, with one of these comments arguing that species belonging to the same genus are closely related and thus have a high degree of biochemical similarity even though they may not be sexually compatible. The commenter also cited the history of safe use of foods from plant varieties developed through plant breeding. EPA also received comments expressing serious reservations about using, for this exemption, a taxonomic standard for describing closely related plants (i.e., Option 2), because taxonomic categories, and the relationship of a given plant species to a given taxon, may be transient since taxonomic categories may change as information accrues. Others expressed concern that dietary risk may be presented by such a standard.

EPA received 37 comments on the use of the process by which the genetic material is introduced into the plant as an exemption criterion. Twenty of these comments supported an approach based on process, i.e., that those plant-incorporated protectants introduced by rDNA would be regulated. The arguments advanced by these commenters can be represented by the comment that:

> Genetic engineering (particularly recombinant DNA [rDNA] methodologies), represents a fundamental technical advance over traditional plant breeding in the ability to manipulate plants genetically. Genes which code for production of plant-pesticides can be readily turned 'on' or 'off' to dramatically increase the existing levels of plant-pesticides within plants, turning plants into pesticide factories and delivery systems. . . . given the fact that rDNA technologies represent such a fundamental technical advance over plant breeding, and given that plant-pesticides are by their very nature toxic substances, all plant-pesticides produced via rDNA methodologies should undergo some form of review under both FIFRA and FFDCA . . . (Ref. 3).

Several letters described quantitative changes in the levels of plant-incorporated protectants as specific

instances in which the commenter believed risk would be better addressed by an approach based on process. One of these commenters did not agree with EPA's analysis that levels of the plant-incorporated protectants (and thus of their residues) are likely to fall, in the vast majority of cases, within ranges currently found in safely consumed food from plants. Another of these commenters urged EPA to modify the proposed exemption so that the Agency would be notified if levels of pesticidal substances are ''deliberately increased through the introduction or modification of promoters or other noncoding regulatory sequences or there is reason to believe that levels of a plant-pesticide in food or feed derived from a particular crop will be increased by an order of magnitude or more'' (Ref. 3).

In response to the May 16, 1997, supplemental document, EPA received six comments. Five comments supported exemption of residues of plant-incorporated protectants derived from sexually compatible plants, with four comments addressing specific questions posed by EPA. One commenter, however, opposed any exemption that did not take into account quantitative changes in the levels of these residues, stating that ''current knowledge is certainly inadequate to sanction greatly increased levels of these substances'' in food (Ref. 4).

Some comments urging regulation based on whether rDNA had been used to introduced the plant-incorporated protectant, supported exempting conventional breeding. One commenter, for example, stated ''that a long record of experience with the products of natural evolution and traditional breeding shows that they typically do not present new dietary exposures and should be exempt from tolerance requirements'' (Ref. 5).

Based on the advice of the BSAC and SAP at the joint meeting held January 21, 1994, and the comments received in response to the November 23, 1994 **Federal Register** document, EPA has determined that it is appropriate at this time to exempt from the FFDCA tolerance requirement those residues of the pesticidal substance portion of plant-incorporated protectants, as well as any inert ingredients derived through conventional breeding from plants sexually compatible with the recipient plant. In a companion document published elsewhere in this issue of the **Federal Register**, EPA solicits public comment on alternative options for the category of residues of pesticidal substances derived through the techniques of modern biotechnology, e.g., recombinant DNA, from plants sexually compatible with the recipient plant. The Agency is considering these options in response to public comment on its earlier proposals. One of these options would establish notification procedures, and as the public has not had an opportunity to comment on either the procedures themselves, or the criteria on which EPA would base its regulatory decisions, the Agency believes it would be appropriate to seek additional public comment prior to adopting a particular option. In addition, as these alternatives would distinguish between categories of residues of plant-incorporated protectants based solely on the processes by which they are derived, the public will also have an opportunity to present comments on whether this is an appropriate distinction for regulatory purposes.

C. What is the Language of the Exemption?

In this final rule, EPA is, at 40 CFR 174.479, exempting only a subgroup of the category of residues it proposed to exempt in 1994, pesticide chemical residues derived through conventional breeding from plants sexually compatible with the recipient plant. EPA discusses the language of the exemption as it applies to this subcategory.

1. *Why is sexual compatibility an appropriate standard?* EPA believes that sexual compatibility is an appropriate standard because sexually compatible plants share a common pool of genetic material, even though there may be some variability among plants in sexually compatible populations. Sexual compatibility, the ability to produce viable offspring, is only possible in nature for plants that possess many traits in common. Traits, and the genetic material encoding them, can be passed through sexually compatible plant populations by hybridization, and the mixing of genetic material that occurs through this process of mating tends to a situation where the members of sexually compatible population have similar traits and similar genetic material. This is particularly true with crop plants where generations of selection and breeding have tended to increase the homogeneity of traits used to produce agriculturally important cultivars. Sexual compatibility thus presents a natural grouping of plants which can be readily described and used as a regulatory standard, and about which a large amount of information exists in the scientific literature. This information can be used in assessing risk.

Using sexual compatibility as a standard affords a clear delineation of whether the residues of a plant-incorporated protectant meet the conditions of the exemption. In most cases, whether two plants are sexually compatible is known; thus, testing to determine whether the plants are sexually compatible is not likely to be necessary. If, in rare cases, it is not known whether two plants are sexually compatible, the means of determining sexual compatibility is straightforward and simple. Sexual compatibility is empirically demonstrable. EPA believes that the criterion of sexual compatibility provides a high level of regulatory clarity and the greatest ease of implementation, while at the same time presenting the lowest probability of novel dietary exposure. This standard allows the public, industry, and EPA to easily and readily identify those plant-incorporated protectants that meet the criterion of being derived from plants closely related to the recipient plant.

i. *Why is sexual compatibility limited to conventional breeding?* As explained in a companion document published elsewhere in this issue of the **Federal Register**, EPA is soliciting additional comment on the various options it is considering in response to the significant comments it has received raising issues specific to plant-incorporated protectants derived through genetic engineering. Because none of the comments raised significant issues relative to pesticide chemical residues of plant-incorporated protectants derived through conventional breeding, the Agency is finalizing its proposals with respect to residues of this subgroup of products. In a final rule under FIFRA described elsewhere in a companion document in this issue of the **Federal Register**, EPA includes in the definition of sexually compatible at 40 CFR 174.3 the clause ''through conventional breeding.'' EPA also provides a definition of conventional breeding that equates it to the creation of progeny through either: The union of gametes, i.e., syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses; or vegetative reproduction. Conventional breeding does not include use of any of the following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion. EPA believes that this

definition addresses the recommendation of the SAP/BSAC that ''the Agency define methodologies in a way that clearly delineates to the scientific community and the public what is and is not included in the regulatory scope'' (Ref. 6).

In the 1994 proposed rule (59 FR at 60538) and in the 1997 supplemental document (62 FR at 27135), EPA states that its proposed rule is based on ''experience with the exposure of human populations to crops developed through the breeding process, i.e., crops developed through 50 to 100 years of scientific breeding among sexually compatible plant populations using Mendelian genetics.'' In its 1994 proposed rule, EPA calls this type of breeding, ''traditional breeding'' (see e.g., 59 FR 60519). When the Agency determined that it would exempt a subgroup of residues of the sexually compatible grouping, while allowing additional comment on how the Agency should treat the residues of those plant-incorporated protectants introduced into the plant through the techniques of modern biotechnology, EPA chose to describe the exempt group of residues in the most straightforward manner, as those derived through breeding in sexually compatible populations. Recognizing that many consider the modern techniques of biotechnology as simply an extension of breeding techniques, EPA determined that an adjective was needed to modify the word ''breeding'' to adequately describe the exempt group. Although the Agency used the word ''traditional'' in its 1994 proposed rule, EPA chose the word ''conventional'' to describe this type of breeding in this rule because the SAP/BSAC in the report of their January 21, 1994 joint meeting used the adjective ''conventional'' in its advice to EPA (Ref. 6), and the word ''conventional'' might more readily connote techniques such as wide crosses.

ii. *Why is conventional breeding described by processes such as pollination and vegetative reproduction?* One comment received on the 1994 proposed rule suggested that there is ambiguity in the proposed regulatory language at 40 CFR 174.5(a) in the November 23, 1994, **Federal Register** document (59 FR 60535). The commenter indicated the perceived ambiguity could lead to questions about whether plant-incorporated protectants that are ''native'' to a food crop would meet the criteria of exemption.

Because of the use of the word ''food'' in the comment, it was not clear whether the comment is directed toward EPA's proposed exemption under FIFRA or that under the FFDCA for residues of plant-incorporated protectants derived from plants sexually compatible with the recipient plant. EPA assumes this comment is directed at both exemptions, and that the commenter's suggestion is that EPA ensure that the regulatory language exempts from the FFDCA tolerance requirements, residues of those plant-incorporated protectants that normally occur in a plant (i.e., are ''native'' to the plant) and will be used in that plant. For example, if corn normally produced a plant-incorporated protectant, the regulatory text should be clear that the residues of the plant-incorporated protectant would be exempt when produced and used in corn. EPA believes inclusion of the word ''pollination'' as an example of a process leading to syngamy in the definition of conventional breeding addresses this concern. EPA believes the word ''pollination'' is appropriate because pollination is the process through which traditional breeding occurs (see e.g., 59 FR 60537) (Ref. 7). Inclusion of the word ''pollination'' in the definition emphasizes that plant-incorporated protectants that occur naturally in a plant growing from a viable zygote that arises by the mating in conventional breeding of one corn variety with another, or the mating of a corn plant with a corn plant of the same variety, are exempt.

EPA recognizes that this same concern also applies to plant-incorporated protectants in plants that are propagated vegetatively. EPA believes inclusion of the phrase ''vegetative reproduction'' in the definition of conventional breeding addresses this concern. The language of the exemption for pesticide chemical residues derived through conventional breeding from sexually compatible plants specifically exempts residues in plants reproduced vegetatively. For example, residues of a plant-incorporated protectant in a plant propagated only vegetatively, (e.g., bananas), are exempt. Also exempt are residues of a plant-incorporated protectant in a plant propagated primarily vegetatively (e.g., potatoes), as long as, under conditions of reproduction through hybridization, the plant donating the genetic material is sexually compatible with the recipient plant as defined in at 40 CFR 174.3, and the other conditions described at 40 CFR 174.479 are met. Inclusion of this term in the definition of conventional breeding reflects EPA's statement in the 1994 proposed rule (59 FR 60524) on the status of crop plant varieties propagated vegetatively.

iii. *Will wide and bridging crosses be part of the definition of conventional breeding?* In the final rule under FIFRA described elsewhere in a companion document in this issue of the **Federal Register**, EPA defines ''conventional breeding'' to include wide and bridging crosses. These definitions are also important to this FFDCA tolerance exemption, and thus, EPA discusses them in this preamble.

In the final rule, wide crosses include use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre-pollination and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture or ovary and ovule cultures. Generations of artificial hybridizations through these techniques have taken place in the well-established practices of plant breeding (Ref. 8). Wide crosses, have been in the past and are currently, commonly used to expand the plant gene pool for varietal improvement, and a history of safe use has been associated with plant varieties developed through the use of wide cross techniques (Ref. 8). A fairly high degree of relatedness between the parental plants is indicated when a wide cross produces a viable zygote. This high degree of relatedness indicates a low probability of new exposures. Agricultural plants safely consumed as food have been developed in the past 100 years utilizing wide crosses in the breeding process.

The definition of ''bridging crosses between plants'' is intended to convey the concept that an intermediate plants could be used in a cross to move traits from a source plant into a desired recipient plant. The intermediate plant can form viable zygotes with both the source and recipient plants, whereas the source and recipient plant cannot form viable zygotes. The intermediate plant serves as a bridge for gene flow between the two incompatible plants. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote. No comments were received on the proposed definition of bridging crosses between plants, also part of the definition of conventional breeding for sexually compatible. EPA is adopting this definition as proposed.

iv. *Will cell or protoplast fusion be part of the definition of wide crosses?* EPA received one comment suggesting that protoplast fusion should be included in the definition of wide crosses between plants. That request was made in the context of the proposal to exempt plant-incorporated protectants derived from plants sexually

compatible with the recipient plant from FIFRA requirements, but as the definition of wide crosses is also relevant for this FFDCA exemption, EPA will discuss that comment in this preamble.

In the technique of protoplast fusion, protoplasts are made in the laboratory through the removal of the cell walls of somatic cells. A somatic cell is a type of cell that forms plant vegetative tissues and organs and is distinguished from a germ cell which undergoes meiosis to produce reproductive tissues (e.g., pollen and egg cells). In the technique of protoplast fusion, protoplast are made from the somatic tissues of two different plants. The membranes of the different protoplasts are then fused together mechanically through processes such as treatment with polyethylene glycol, producing a hybrid somatic cell with a genetic make-up resulting from the combination and sorting of the two plant genomes. The somatic hybrid cell is then grown on specialized media into a mature plant.

In support of the request, the commenter argued that the hybridization of somatic cells (i.e., protoplast fusion) has a history of use to artificially induce sexual compatibility. The commenter argued that movement of genetic material by this means has historically been considered safe.

EPA did not, in its 1994 proposed rule include protoplast fusion in the definition of wide crosses between plants, nor did it perform an analysis of the potential for new dietary exposures when protoplast fusion is used to perform wide crosses between plants. The commenter did not provide such information in response to the 1994 proposed rule nor the 1997 supplemental document. EPA does not believe information currently in the record supports inclusion of protoplast fusion in the definition of wide crosses. Therefore, EPA does not include protoplast fusion in the definition of wide crosses and specifically excludes cell fusion from the definition of conventional breeding. However, EPA requests comment on whether protoplast fusion should be included in the definition of wide crosses in a supplemental document published elsewhere in this issue of the **Federal Register**. EPA would welcome submission of information on protoplast fusion. If the Agency obtains sufficient information demonstrating a low probability of risk, EPA may initiate notice-and-comment rulemaking under FIFRA section 25(b) and FFDCA section 408 to include protoplast fusion in the definition of wide crosses between plants.

v. *''Recombinant DNA'' and genetic material ''extracted from an organism and introduced into the genome of the recipient plant.''* As explained previously, EPA restricted this exemption to conventionally bred plant-incorporated protectants while the Agency solicits additional comment on the alternatives it is considering in response to the comments received on the 1994 proposal. Thus, in order to fully describe which plant-incorporated protectants are exempt under this exemption, EPA includes limiting phrases. EPA in the 1994 **Federal Register** document (59 FR 60541, November 23, 1994) discussion of the advice of the joint SAP/BSAC at the January 21, 1994 meeting on the use of a process-based criterion to define a category of plant-incorporated protectants that would be subject to review, stated that the Agency would define such a process-based criterion in the following way: ''The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is extracted from an organism and introduced into the genome of the recipient plant or is synthesized *in vitro* and introduced into the genome of the recipient plant.'' EPA in this action uses the language it put forth in the 1994 **Federal Register** to fashion two of the exclusions from the conventional breeding definition at 40 CFR 174.3. One exclusion is for techniques involving the direct introduction into an organism of genetic material extracted from the source and introduced into a recipient plant. Processes such as micro-injection, macro-injection and micro-encapsulation would be excluded from the conventional breeding definition because they are used to introduce such extracted genetic material into the recipient plant. These processes have been included in the definition as examples to assist in understanding the concept.

The second exclusion from the conventional breeding definition uses the term ''recombinant DNA'' to represent the concept of ''extracted from an organism. . ., synthesized *in vitro* and introduced into the genome of the recipient plant.'' To provide greater technical accuracy, EPA provides a definition at 40 CFR 174.3 for recombinant DNA as follows: ''Recombinant DNA means the genetic material has been manipulated *in vitro* through the use of restriction endonucleases and/or other enzymes that aid in modifying genetic material, and subsequently introduced into the genome of the plant.''

2. *Why is the concept of ''functionally modified from the source'' important and how does the definition of conventional breeding address it?* In the November 23, 1994 **Federal Register** document (59 FR at 60539), EPA explained that in proposing the exemptions the Agency did not intend to exempt residues of a pesticidal substance that is significantly different functionally, from the pesticidal substance as it occurs in the source plant. EPA believed this limitation is appropriate because rearrangements or modifications of the genetic sequence encoding a pesticidal substance made through the use of techniques such as rDNA could, for example, result in a plant-incorporated protectant, and/or residues of such a plant-incorporated protectant, with significantly different functions from the function in the source plant. For example, if the pesticidal substance is an enzyme, it could be modified so that it acts on a different substrate in the recipient plant than it did in the source plant (Refs. 8 and 9). Residues of such a significantly modified pesticidal substance would not necessarily present risks similar to the substance prior to modification, nor would the base of experience on which EPA relies for support of the exemption necessarily be relevant. If the genetic material encoding the pesticidal substance has been modified in such a way that the pesticidal substance functions differently in the recipient plant than it did in the source plant, the analysis performed to determine that there is a reasonable certainty that no harm will result from aggregate exposure to the residues of the plant-incorporated protectant, would not apply.

In this final rule, this concern is addressed by the limitation placed on the definition of sexually compatible. Under this definition, residues of pesticidal substances from sexually compatible plants are only exempt if the genetic material is introduced into the plant through conventional breeding as defined at 40 CFR 174.3. The types of changes discussed above (Refs. 8 and 9) that can be made through modern molecular techniques, are very unlikely to be made through conventional breeding as defined at § 174.3, and residues of plant-incorporated protectants modified through modern molecular techniques are not eligible for today's exemption.

3. *Why is the phrase ''never derived from source not sexually compatible with recipient plant'' important?* EPA discussed the relevance of this phrase to the proposed exemption in the November 23, 1994 **Federal Register**

document (59 FR 60539). The phrase, ''has never been derived from a source that is not sexually compatible with the recipient plant,'' was included in the proposed regulatory text to clearly indicate that pesticide chemical residues of a plant-incorporated protectant would not qualify for the exemption if the genetic material is introduced into a recipient plant from a sexually incompatible source and then subsequently introduced from this recipient plant into other plants sexually compatible with the recipient plant. For example, the exemption does not extend to a situation where the genetic material encoding the *Bacillus thuringiensis* delta endotoxin is introduced into wheat, and the endotoxin-producing wheat is subsequently hybridized with rye using wide cross techniques to produce triticale. The residues of the endotoxin produced in the triticale would not be eligible for the exemption because the genetic material encoding the endotoxin originated from a bacterium, a source that is not sexually compatible with the original recipient plant (wheat in this example).

One commenter suggested that the Agency delete this phrase from the regulatory text and instead include a period of time after which a plant-incorporated protectant would be treated as part of a plant's ''accessible'' gene pool. EPA disagrees and will continue to include this language in the final rule at 40 CFR 174.479. Further, EPA disagrees with the commenter's suggestion that a gene, derived from a phylogenetically distant source and successfully used in a crop, be treated after a period of time as though it had become part of the crop's gene pool (i.e., equivalent to a gene that had evolved in a sexually compatible population of plants). The commenter does not suggest what an appropriate period of time would be nor how this would correlate with the potential for dietary exposures. Without additional information, EPA cannot find that there is a ''reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue'' as required by FFDCA section 408(c).

4. *Why is EPA placing a condition on the exemption limiting the levels of pesticidal substances?* To address concerns raised in comment on its original proposal concerning the possibility that certain substances normally present in plants in sexually compatible populations may in rare circumstances be present in food at levels that are hazardous, EPA is limiting this exemption by requiring that the residues of the pesticidal substance not be present in food from the plant at levels that are injurious or deleterious to human health. EPA is including at 40 CFR 174.479, the following condition to the language of the exemption: ''(c) The residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health.''

If the residues of the plant-incorporated protectant do not meet this criterion, they are not exempt from the requirement of a tolerance, nor would a tolerance have been established for them. A food containing residues of a pesticide may not be moved in interstate commerce without either an appropriate tolerance or an exemption from the requirement of a tolerance. Should such an occurrence be identified, the condition will allow expeditious removal of the offending food from the market. EPA does not believe that such an occurrence will result *a priori* in a reevaluation of the categorical exemption for pesticidal substances derived through conventional breeding from sexually compatible plants under FFDCA section 408 because any problem will likely be associated with a single variety.

Producers who wish to increase the levels of pesticidal substances in plants in sexually compatible populations beyond the ranges of levels generally seen in plant varieties currently on the market and known to produce food safe for consumption are strongly encouraged to consult with EPA to determine whether their plant-incorporated protectant is eligible for the exemption from the requirement of a tolerance, or whether a tolerance, and therefore, a registration is necessary. Based on the record compiled for this rulemaking on the historical safety of food from plants in sexually compatible populations, as described in Unit IX.A. and Unit IX.B.1., EPA believes that such a circumstance, will be extremely unlikely for residues derived through conventional breeding from plants sexually compatible with the recipient plant.

This condition makes EPA's approach to plant-incorporated protectants more consistent with FDA's regulatory approach, and allows the agencies to act more expeditiously in the rare circumstance that a risk associated with higher levels of substances normally part of a plant in a sexually compatible population is identified in food.

This condition, in conjunction with the reporting requirement at 40 CFR 174.71, is conceptually similar to the suggestion of one commenter that the Agency be notified if levels of pesticidal substances are significantly increased. EPA disagrees, however, with the commenter's suggestion that notification be required only when levels of pesticidal substances are increased by 10 fold. There is natural variability in levels of expression in a plant of any substance, including plant-incorporated protectants, influenced by factors such as genetic composition, soil composition, climate and weather. Humans are currently being exposed to variation in the food they consume. The commenter did not provide information to support the suggestion that a 10-fold increase would represent an unacceptable risk, and broad adoption of such a standard would be arbitrary. The variations normally seen in food from plants, such as the 20-fold variation for ascorbic acid in muskmelon depending on variety planted, and the variation in the levels of carotene in carrots which can range from none detectable to 370 mg/100 g tissue depending on the variety (Ref. 8), are greater than the 10-fold increase suggested by comment. Other examples can be offered where the variation falls within a more narrow range, for example, one researcher (Ref. 8) reported that depending on maturity of the fruit, the level of ascorbic acid in tomato can range from 2.7 mg/100 g tissue to 7.6 mg/100 g tissue, a 2.8-fold variation. The conditions on the exemption at § 174.479 and reporting requirement at § 174.71, on the other hand, have no numerical standards. Nevertheless, the Agency believes that the adverse effects reporting requirement will allow the Agency to monitor for any rare instances in which significant increases in levels of plant-incorporated protectants might present a hazard, and that the condition at § 174.479 will allow EPA and FDA to act expeditiously. (The adverse effects reporting requirement is described in a companion document published elsewhere in this issue of the **Federal Register** on FIFRA regulations for plant-incorporated protectants).

The historical safety of the food supply as described by the record EPA has compiled for this exemption, the reporting requirement imposed as a condition of the FIFRA exemption, taken in conjunction with the strong likelihood that manufacturers and companies will choose to consult with EPA rather risk seizure of their food by FDA, cause EPA to believe that the condition placed on the exemption sufficiently address the commenters' concerns.

5. *Why does 40 CFR 174.479 include language limiting the recipient to food plants?* In the preamble to the 1994

proposed rule (see e.g., 59 FR 60537), EPA discussed the premise for this exemption; that ''new dietary exposures would not likely arise for plant-pesticides produced in recipient food plants if the genetic material leading to the production of the pesticidal substance is derived from closely related plants.'' In addition, the BSAC in its report on the July 13, 1993 meeting (Ref. 10) emphasized to the Agency that the focus of an exemption should be on plant-incorporated protectants in food plants. They suggested that ''plant-pesticides in plants commonly consumed by humans as food be exempt as long as the plant's genetic material is derived from related plants within the same family that have contributed traits to the food plant through the mechanism of sexual recombination (including wide crosses and embryo rescue)'' (59 FR 60540). In this final rule, EPA has revised § 174.479 to clearly state that the recipient plant must be a food plant by including the phrase ''recipient food plant'' in the regulatory text at § 174.479(a) and (b). In the final rule, EPA has revised the definition of ''food plant'' proposed in the 1994 proposed rule at 40 CFR 180.1137 (59 FR at 60542) to read: ''Food plant means a plant which, either in part or in toto, is used as food''. EPA includes this definition at 40 CFR 174.3. EPA also includes at § 174.3 the definition of food found in the FFDCA. Thus, for these regulations for plant-incorporated protectants: Food includes articles used for food or drink by humans or other animals.

6. *What is the status of substances within sexually compatible plant populations that might be used as inert ingredients?* In a companion document published elsewhere in this issue of the **Federal Register**, EPA describes its consideration of inert ingredients in light of existing regulations and comments received in response to both the November 23, 1994 **Federal Register** document (59 FR 60534) and a 1996 supplemental document (61 FR 37891) discussing the Agency's treatment of selectable markers as inert ingredients for plant-incorporated protectants. In the companion document published elsewhere in this **Federal Register** on FIFRA regulations, EPA describes its determination that it will apply the concept of inert ingredients to plant-incorporated protectants consistent with the 1994 proposal.

The preamble discussion in the 1994 **Federal Register** document (59 FR at 60523) of the rationale supporting the proposal to exempt plant-incorporated protectants derived from sexually compatible plants extends to any substance that is derived from plants sexually compatible with the recipient plant, including substances such as a selectable marker, used to confirm or ensure the presence of the active ingredient. EPA's analysis in Unit IX., applies equally to all the substances that normally are found in a population of sexually compatible plants, including inert ingredients as long as these are derived through conventional breeding from plants sexually compatible with the recipient plant, and have never been derived from a source that is not sexually compatible with the recipient plant. An example of such an inert ingredient in sexually compatible populations could be tightly linked traits, such as unusual leaf pigmentation always found with a pest resistance trait.

EPA includes these residues at 40 CFR part 174, subpart X, to ensure that readers understand that any trait used as a selectable marker, and the genetic material necessary to produce it, that occurs normally in a plant sexually compatible with the recipient plant or is introduced through conventional breeding, is exempt from the FFDCA section 408 requirement of a tolerance, as well as FIFRA requirements on inert ingredients when used with a plant-incorporated protectant derived through conventional breeding from a plant sexually compatible with the recipient plant. EPA believes this interpretation is a logical implication of the preamble discussion in the 1994 proposed rule (59 FR at 60538).

Because the Agency recognizes that a substance described in Unit IX.B.2. (i.e., a toxicant) could theoretically be used as an inert ingredient, EPA places the same limiting condition on residues of the inert ingredient in food as is placed on residues of the pesticidal substance portion of the active ingredient; i.e., the residues of the inert ingredient do not qualify for the exemption if they are present in food from the plant at levels that are injurious or deleterious to human health.

Discussion supporting this exemption can also be found in a companion document published elsewhere in this issue of the **Federal Register** on FIFRA regulations for plant-incorporated protectants. Regulatory text has been established at 40 CFR 174.485, subpart X, which is entitled ''Inert ingredients from sexually compatible plant,''in a companion document on FIFRA regulations for plant-incorporated protectants published elsewhere in this issue of the **Federal Register**.

D. What Were the Other Potential Approaches to the Scope of Exemption?

In the November 23, 1994 **Federal Register** document (59 FR 60537), EPA discussed the merits of an approach using taxonomy, along with sexual compatibility (Option 2), as a standard for describing closely related plants, and received comment on use of such a criterion. EPA also received a comment, made in the context of the FIFRA regulations, suggesting that the criterion of sequence homology be used to limit the concept of sexual compatibility. In light of the relevance of this comment to this FFDCA exemption, EPA discusses this suggestion, as well as the comments on taxonomy, here. EPA also discusses a comment suggesting that EPA consider extending the exemption, on a case-by-case basis, to residues of plant-incorporated protectants derived from plants unrelated to the recipient plant, and a suggestion that exemptions should be based on a documented history of safe use.

1. *Taxonomy*. Two commenters expressed reservation about using a taxonomic standard for describing closely related plants. They pointed out that taxonomic categories, and the relationship of a given plant species to a given taxon, may be transient since taxonomic classification may change as information accrues. EPA agrees. In the 1994 **Federal Register** document, EPA noted (59 FR at 60524) that a taxonomy-based standard (e.g., Option 2) may be artificial: classification of plants in different taxonomic genera is not fixed and could change over time and between scientific authorities. Taxonomy reflects current observations about phenotypic, and to some extent, genotypic, differences between organisms. Currently, some plant genera are narrowly defined; for other plant genera, membership is based on broader criteria. These differences in classification criteria may lead to different probabilities between genera that new exposures may occur when genetic material from one species in a genus is introduced into another species in the genus. In recent years new tools have become available to taxonomists, allowing them to better clarify phylogenetic relationships among organisms. New information, particularly that obtained through the use of new genetic tools, concerning organisms' properties and relationships may in the future alter current taxonomic designations. In light of these advances, EPA anticipates there may be some reorganizations among the Plantae, and that these reclassifications will better reflect the relationships

among plants, and the probability of new exposures in intrageneric crosses.

The possibility that taxonomic classification may change as information accrues would add an extra layer of complexity to any regulations based on a taxonomic standard, and EPA probably would not be able to structure an exemption to accommodate for potential changes in classification. The possibility of reclassification also creates some uncertainty within the regulated community about the future status of a product.

Furthermore, under the FFDCA, an exemption must be examined specifically within the context of the food supply and dietary consumption. Although some species in a genus might be food plants, others in that genus might not. Moreover, in a genus containing food plants, there may be such barriers to hybridization that some of the non-food species in that genus would never have contributed to the food supply. Thus, there may be no experience with the potential dietary risks associated with such non-food species. In addition, knowledge of whether substances such as naturally-occurring toxicants are present is, in general, more limited for all the plant species constituting a genus than it is for species used to produce the major food crops. Consequently, there is a greater degree of uncertainty in any finding applicable to all potential members of taxonomic categories. The large body of information supporting this exemption was generated for food crops in sexually compatible populations (Refs. 8, 11, 12, 13, 14, 15, 16, 17, 18, and 19, for example). Overall, the base of dietary experience is not as broad or as deep for populations of plants described by the taxonomic standard of genus as it is for populations of plants described by sexual compatibility. EPA does not believe it possesses sufficient information at this time to allow the Agency to issue an exemption based on taxonomy.

2. *Sequence homology*. EPA received one comment suggesting that an additional criterion be used to limit the concept of sexual compatibility. While this suggestion was made in the context of a comment made on the proposal to exempt plant-incorporated protectants derived from plants sexually compatible with the recipient plant from FIFRA requirements, EPA discusses that suggestion here because of its relevance to EPA's decision to exempt residues of pesticidal substances derived through conventional breeding from plants sexually compatible with the recipient plant. The suggested criterion of sequence homology would base relatedness on the degree of sequence homology between the source and recipient plant. Sequence homology refers to the extent that the sequence of deoxynucleotides in two pieces of genetic material are the same. A deoxynucleotide is made up of a sugar, a phosphate, and one of four purine or pyrimidine bases (adenine, cytosine, guanine, thymine). The sugars and phosphates of the deoxynucleotides are covalently linked by phosphodiester bonds to form the ''backbone'' of the deoxynucleotide polymer (DNA). One base is attached to each sugar in the sugar-phosphate backbone. The information encoded in the genetic material is determined by the sequence in which the bases are attached to the sugar-phosphate backbone. The extent to which two pieces of genetic material have the same base sequence is often described in terms of percent homology, with 100% homology meaning the pieces of genetic material have an identical sequence. The Agency currently believes that DNA sequence homology is a less straightforward standard for regulatory purposes than a standard such as sexual compatibility. Sexual compatibility is known in most cases, and if it is not, it is less burdensome and simpler to demonstrate than is relatedness based on DNA sequence homology. Use of homology as a criterion presents the following complex issues. First, where should homology be assessed? For example, how many genes of the source and recipient plants should be compared to determine the degree of homology? All the genes of both plants? A few genes? If only a few, which genes? Second, what degree of homology would be sufficient to indicate a high degree of relatedness? Third, under what conditions should homology be measured? Fourth, appropriate test procedures would need to be developed and validated in order to set a standard procedure for measuring homology. All of these issues would need to be resolved, and converted into regulatory text, in order to develop an exemption standard based on DNA sequence homology.

3. *Other potential exemptions suggested by comment*. One comment suggested that EPA consider extending the exemption, on a case-by-case basis, to residues of the pesticidal substance portion of plant-incorporated protectants derived from plants unrelated to the recipient plant: ''Should a gene be taken from a commonly consumed food plant and inserted into another commonly used food plant, and the trait is expressed at approximately the same (or lower) level, an exemption would be warranted.'' A second commenter proposed that exemptions should be based on a documented history of safe use.

With regard to the suggestion that EPA consider extending exemptions on a case-by-case basis to residues of pesticidal substances of plant-incorporated protectants derived from plants unrelated to the recipient plant, the Agency has the option to exempt residues of pesticides from the requirement of a tolerance on a case-by-case basis provided that the residues meet the exemption standard in FFDCA section 408(c). In addition, any person may petition EPA to establish a tolerance exemption pursuant to section 408(d). Section 408(d)(2)(A) establishes the minimum requirements for such a petition. As additional information becomes available, EPA will consider, in future, exempting from the FFDCA requirement of a tolerance, residues of plant-incorporated protectants derived from plants unrelated to the recipient plant when these can be shown to meet the FFDCA section 408 safety standard. EPA also has the option of exempting residues of plant-incorporated protectants based on a history of safe use where there is sufficient information to meet the FFDCA section 408(c) test.

IX. Statutory Finding

A. What Methodology Did EPA Use to Assess these Residues?

For most pesticides (e.g., chemical pesticides), EPA's dietary risk evaluation relies on data generated by testing in laboratories using representative animal models to estimate acute, subchronic or chronic hazard end-points (e.g., acute toxicity, carcinogenicity, developmental toxicity). Conclusions from animal models are used to assess dose-response and describe such endpoints for potential human hazard. Other information, including residue data and information generated by use of mathematical models, are used to develop human exposure estimates. These exposure and hazard components are combined to quantify the potential risk associated with the pesticide's use. Uncertainty factors are often used in the risk assessment to account for extrapolation from animal models to human toxicity and from limited studies using humans to the larger population. The data requirements describing the types of information to be generated and other guidance for assessing dietary risk are detailed in 40 CFR part 158.

The questions posed as part of the risk assessment in evaluating residues of

most pesticides (e.g., chemical pesticides) can also be posed for the pesticide chemical residues that are the subject of this exemption, and 40 CFR part 158 can be used as guidance in evaluating these residues for hazard end-points (including, for example, acute toxicity, carcinogenicity, and developmental toxicity). To address the hazard endpoints described in 40 CFR part 158 for residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants, EPA relied on a very large body of information found, for the most part, in the public scientific literature. In performing the assessment for this exemption from the requirement of a tolerance, EPA did not need to rely as much on information generated from animal models as it would in assessing other pesticides (e.g., chemical pesticides). A very large body of experience with actual human dietary consumption over hundreds, if not thousands, of years exists for the substances that are the subject of this exemption. And thus, a large and varied amount of information developed through systematic scientific study exists in the literature, and can be used for assessing the risk of exempting these residues. Numerous epidemiological studies on humans show the health benefits of consuming foods containing residues of the plant-incorporated protectants that are the subject of this exemption (Refs. 11, 12, 13, 14, 15, 16, 17, 18, and 19). The epidemiological studies in particular provide information on the effects of chronic exposure of a far longer term than is possible with animal model experimentation, given the large differences in life span between humans and most animals used in animal model testing. The results of many nutritional assessment studies using human volunteers are available on the effects of either whole foods from plants in sexually compatible populations or isolated constituents from food from such plants (Refs. 11, 12, 13, 14, 15, 16, 17, 18, and 19). Studies have also been performed using animal models to test the effects of either whole foods from crops in sexually compatible populations or constituents from food from such crops (Refs. 11, 12, 13, 14 15, 16, 17, 18, and 19). There is a large literature on constituents of food from plants in sexually compatible populations accumulated by a century of systematic study (Ref. 8), and EPA also used these sources of information.

EPA also considered other information in the literature in evaluating the potential for exposure to residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants. Plant-incorporated protectants are produced within the living plant itself and the pesticidal substance is used *in situ* in a living plant to protect against pests, in contrast to most other pesticides which must be applied to the plant (Ref. 20). Because a plant-incorporated protectant is produced and used within the plant, physiological constraints limit the amounts of residues produced by the plant (Ref. 20). Because the plant-incorporated protectant is within the plant, routes by which other organisms may be exposed to the plant-incorporated protectant may be more limited, e.g., dietary exposure is likely to be the predominant route of exposure.

EPA used experimental data derived from the science of phytopathology to characterize the disease and pest resistance mechanisms known to occur in plants (Ref. 21). EPA also considered information from the field of plant physiology regarding plant metabolism, the production of substances that may have pesticidal effects, and conditions that may limit the plant's production of such substances (Refs. 7 and 20). This information also provided a basis for EPA's estimation of the physiological limitations to production in plants of substances that may be pesticidal and thus to production of their residues. EPA also used information from the fields of biochemistry, microbial ecology, and ecology (Refs. 7, 21, and 37).

EPA's conclusion that the vast majority of plant varieties developed by conventional breeding in sexually compatible populations produce foods that are safe for human consumption is based on this information and the historical consumption of crops since the prehistorical origins of agriculture. EPA also considered its knowledge of the practices that plant breeders routinely employ in selecting and developing plant varieties in sexually compatible plant populations, such as chemical analyses, taste-testing, and visual analyses, and that such practices have historically proven reliable for ensuring the safety of food from such plants (Refs. 8 and 22). EPA also considered that appropriate processing procedures are widely known and are routinely used by consumers in preparation of food containing residues that are the subject of this exemption, including those foods which require specific processing and/or preparation steps to avoid dietary problems.

Residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants were evaluated for dietary risk within the context of the food supply and dietary consumption patterns. In performing its assessment, the Agency considered that the diet includes all of the food items that are customarily eaten by human populations or subpopulations as part of a normal diet. (EPA did not consider that the normal diet includes plants or plant parts consumed in times of deprivation, for religious reasons, in substance abuse or by misidentification. The information base on which EPA relied in performing its risk assessment (Refs. 8, 11, 12, 13, 14, 15, 16, 17, 18, and 19, for example) did not address such plants.)

EPA considered health risks to the general population, including infants and children. Children, and to some extent infants, have always and currently consume food containing residues that are the subject of this exemption. EPA's risk assessment also included subgroups as part of the general population, (i.e., differences in diet due to the influence of culture), and allowed for consumption pattern differences of such subgroups. The consumption of food plants is part of a balanced and varied diet.

EPA believes that the numerous epidemiological and nutritional assessment studies found in the literature of human experience in consuming food containing residues that are the subject of this exemption, combined with information generated from animal model testing and biochemical studies and knowledge from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry, and plant breeding form the appropriate information base for evaluating the potential risks of such residues.

B. What Factors Has EPA Considered in Making the Findings Required by 408(c) of the FFDCA?

FFDCA section 408(c)(2)(B) requires EPA to consider several factors in determining whether to exempt a pesticide from the requirement of a tolerance (21 U.S.C. 346a(c)(2)(B)). Information relevant to EPA's consideration of these factors with regard to this exemption of the pesticide chemical residues of a plant-incorporated protectant derived through conventional breeding from sexually compatible plants, is contained in this document, as well as in other

documents in the record for this rule as described in Unit X.

The preamble discussion in the 1994 **Federal Register** document (59 FR at 60538), and in the May 16, 1997, supplemental document (62 FR 27132), of the rationale supporting the proposal to exempt residues of plant-incorporated protectants derived from sexually compatible plants extends to any substance that is normally a component of a population of sexually compatible plants. It thus, applies to any substance, such as a selectable marker, used to confirm or ensure the presence of the active ingredient, that is also derived from plants sexually compatible with the recipient plant. EPA's analysis in Unit IX., applies equally to all the substances that are normally a component of a population of sexually compatible plants, including inert ingredients as long as these are derived through conventional breeding from plants sexually compatible with the recipient plant, and have never been derived from a source that is not sexually compatible with the recipient plant.

1. *Validity, completeness and reliability of available data.* As described in Unit IX.A., EPA's risk assessment for residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants was based primarily on an analysis of the long human experience with breeding and growing agricultural plants and preparing and consuming food from such plants, and associated epidemiological studies, nutritional assessments with human volunteers and animal model testing (Refs. 8, 11, 12, 13, 14, 15, 16, 17, 18, and 19). EPA combined this information with knowledge from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry (including studies on the constituents of food), and plant breeding to evaluate the potential risks of pesticide chemical residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants. EPA considered the validity, completeness and reliability of the available information on human consumption of food containing substances that are the subject of this exemption including epidemiological studies, nutritional assessments with human volunteers and animal model testing, as well as information from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry (including studies on the constituents of food) and plant breeding. EPA concluded that this information was valid, complete and reliable, and adequately addressed the issues of hazard and exposure with regard to residues in food of plant-incorporated protectants derived through conventional breeding from sexually compatible plants.

2. *Nature of toxic effect.* In light of comments raising concern about possible adverse effects from increases in the levels of substances that naturally occur at low levels in food from plants, EPA considered the nature of toxic effects shown by the data described in Unit IX.B.1., above to be caused by substances that might potentially be residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants, should these substances be used as pesticides (i.e., if humans intend to use these substances for preventing, repelling or mitigating any pest) and present at high levels. The examination led EPA to conclude that as the vast majority of substances in plants are not toxic, any of these nontoxic substances, should they be used as plant-incorporated protectants, would not present toxic effects. EPA has identified 21 substances of plant origin that are in foods that could be considered part of a normal diet and could potentially present toxic effects if present at high levels (Ref. 8). (The normal diet does not include plants, or parts of plants, consumed in times of deprivation, for religious reasons, in substance abuse, or by misidentification. The normal diet is considered to be balanced and varied and include food from a variety of sources.) This analysis is based on an accumulation of millennia of human experience and a century of systematic scientific study of food constituents (Ref. 8). The conclusion of the analysis described in Unit IX.B.2., for these 21 substances indicates that they are either: Beyond the scope of the exemption; in foods that are not part of the normal diet of the United States population; and/or, millennia of human experience and use have given rise to procedures, on the part of the plant breeder, the food processor and/or the consumer, that combined with the condition determining eligibility for this exemption, adequately address the risk posed by these substances.

These 21 substances, of the hundreds of thousands of plant-produced substances in food, represent less than one-tenth of 1% of the total number of constituents of food (Ref. 8). Of these 21 substances, seven (acetylandromedol, andromedol, anhydroandromedol, desacetylpireistoxin B, gelsamine, tutin, hyenanchin) are in honey, being ''pass-through'' contaminants of honey introduced by bees collecting pollen from rhododendron, azalea, yellow jasmine, or the tutu tree. (The substances from the tutu tree, tutin and hyenanchin, can cause delirium and convulsions). Similarly, four (cicutoxin, coiinine, methylconiine, conhydrine) of the 21 substances capable of causing toxic effects in the normal diet are pass-through contaminants in the milk of cows that have consumed water hemlock or hemlock. These substances are nervous system stimulants. None of the plant sources of these 11 pass-through contaminants are used or intended to be used as food plants and thus this section 408 exemption does not apply to them. Another of the 21 substances in the normal diet identified as potentially causing toxic effects is nitrate. Exposure to excessive amounts of nitrates can cause methemoglobinemia, a condition in which some portion of the hemoglobin molecules become incapable of binding oxygen. Levels of nitrates high enough to cause such effects can be found in spinach and other green, leafy vegetables subjected to intensive application of high-nitrate fertilizers. Nitrates that enter the plant through uptake of fertilizer applied intensively are not ''produced'' by the plant per se, i.e., they are not biosynthesized by the plant. This exemption is not relevant to such nitrates. The toxic effect presented by high levels of nitrates is generally addressed in agriculture by use of proper fertilization practices.

Of the 21 substances originally identified (Ref. 8), nine of these (solanine, linamarin, lotaustralin, cucurbitacin, vicine, convicine, hypoglycin A, sparteine, beta-N-oxalylamino-L-alanine) are biosynthesized by plants that could be used as food in a normal diet somewhere in the world, and, thus, if used by humans for pesticidal purposes, could potentially be pesticide chemical residues derived through conventional breeding from sexually compatible plants. Three of these nine substances (sparteine, hypoglycin A, beta-N-oxalylamino-L-alanine) are found in food not customarily consumed as part of the normal diet in the United States. Their risks appear to be well known locally where plants containing such substances are consumed, and native methods of processing exist to reduce the potential for toxic effects (Ref. 22).

Sparteine is a quinolizidine alkaloid found in the lupines. The lupines are forage or range crops, but can also be cultivated for feed and have some limited use in human food, primarily as

a ''traditional'' grain used by indigenous cultures in South America and the Mediterranean. The presence in the plant of the quinolizidine alkaloids appears to protect the plant against fungal infection. Reduction of the levels of quinolizidine alkaloids in the plant can result in increased levels of potentially more hazardous mycotoxins. Toxic effects from consumption of food containing higher levels of sparteine include breathing problems, weakness and loss of motor control (Ref. 22, 23). These alkaloids can be removed by cooking, or by rinsing for several days (Ref. 22, 24).

Beta-N-oxalylamino-L-alanine is found in the seeds of the chickling vetch. It is a neurotoxin that can cause spastic paralysis, probably by interfering with the action of the neurotransmitter, glutamate (Ref. 22, 25). Reported cases of toxicity are mostly confined to the Indian subcontinent. Most of the toxin can be leached out by soaking the seeds in hot water for several minutes, followed by cooking.

Hypoglycin A is an amino acid analogue found in the immature ackee fruit that can result in severe hypoglycemia and vomiting. Ackee fruit is primarily consumed in Africa and Jamaica (Ref. 22). The primary method of dealing with the potential adverse effect presented by hypoglycin A is avoidance of (i.e., not consuming) immature ackee fruit.

Of the remaining six substances, two (vicine and convicine) affect a small subpopulation of the United States population. Vicine and convicine are found in the fava bean. Exposure of individuals with the Mediterranean form of an inherited deficiency of the enzyme, glucose-6-phosphate dehydrogenase (G6PD), to these substances in the fava bean can result in an hemolytic anemia. The anemia is manageable (Ref. 26). Physicians attempt to prevent hemolytic episodes by warning patients with the Mediterranean form of G6PD deficiency about the risks of consuming fava beans (Ref. 27). Thus, the primary strategy employed by persons with this G6PD deficiency with regard to food is avoidance of (i.e., not consuming) foods containing fava beans. Drying the beans or exposing them to sunlight reduces the potential for hemolytic episodes (Ref. 22).

Several strategies, including breeding for varieties that produce low levels of the substances and monitoring, as well as general knowledge in the population, reduce the potential for toxic effects to occur with the remaining four toxicants (cucurbitacin, linamarin, lotastralin, solanine). Cucurbitacins are naturally present in edible squash and cucumbers at very low levels. Cucurbitacins are purgatives and impart a bitter taste to the fruit. Cucurbitacins if consumed at extremely high concentrations may cause stomach aches or cramps (Refs. 22 and 28). On rare occasions, in producing seed for cultivated varieties, pollen from a wild relative may contaminate the seed plot, resulting in seeds that may produce higher levels of cucurbitacin. Breeding isolation is employed by seed producers to ensure that such contamination does not occur (Refs. 7 and 22).

Linamarin and lotaustralin (also called phaseolutin) are cyanogenic glycosides (Refs. 8 and 22) biosynthesized by cassava and lima beans. When the plant tissue is damaged, enzymes are released that act on the cyanogenic glycoside to produce hydrogen cyanide. The toxicity of cyanide is due to its ready reaction with the iron atom of the enzyme, cytochrome oxidase. The ability of the cell to utilize oxygen is inhibited by formation of the cytochrome oxidase-cyanide complex. Toxic effects associated with cyanide include neurological disorders, breathing difficulties, and thyroid enlargement (Ref. 22). The lima bean varieties on the United States market today were bred and are monitored to ensure that they produce very low levels of cyanogenic glycosides (Refs. 22 and 29). Imported lima beans are monitored to ensure only low levels of cyanogenic glycosides (Refs. 22 and 29). Similarly, cassava used in the United States today comes from varieties that were bred and are monitored to ensure that they produce very low levels of cyanogenic glycosides. Populations outside of the United States (e.g., Africa) that consume cassava from varieties that produce higher levels of cyanogenic glycoalkaloids are aware of the risk associated with this food and use native methods of processing (peeling, chopping and grinding in running water, also boiling and fermentation) to reduce the cyanogenic glycoside content. Cases of toxicity are observed primarily in these populations when the cassava is eaten without adequate processing, because a scarcity of other food items causes individuals to risk consuming inadequately processed cassava to ease their hunger (Ref. 26). There are also ongoing breeding and monitoring efforts to assist these populations to reduce the cyanogenic glycoside content in cassava varieties grown in their countries.

The glycoalkaloids collectively referred to in this document as solanine are biosynthesized by potatoes, and to some extent eggplant and peppers. A related glycoalkaloid, tomatine, can be found in green tomatoes. The solanines are membrane disruptors. Some members of the class have been shown *in vitro* and through intraperitoneal and intravenous injection to be weak to moderate cholinesterase inhibitors (Ref. 30). While solanine poisoning is very rare, in large doses solanine can cause gastrointestinal tract irritation, including moderate nausea, vomiting and diarrhea, as well as headaches, drowsiness, sweating, changes in blood pressure and heart rate, and edema (Ref. 22). Solanine imparts a bitter taste to the tuber, and at high concentrations solanine can leave a persistent irritation and burning sensation on the tongue (Ref. 22). Potato varieties are bred and monitored in the United States to ensure that they produce only low levels of solanine (Refs. 22 and 31). Monitoring for these glycoalkaloids also occurs during the grading and shipping of potatoes. Peeling or removing any damaged portion of the potato is the best way to reduce solanine levels. In an undamaged, unsprouted potato, thirty to eighty percent of the solanine is found in, and directly under, the skin. Cooking, e.g., boiling in steam or water or deep frying in oil at 170 degrees, may lower solanine concentrations (Refs. 22 and 32).

For the reasons described in the preceding paragraphs, EPA does not believe that this exemption would result in levels in food of residues of these four substances significantly different from those observed in food currently safely consumed. That there have been few instances in the United States of toxic effects on humans due to substances normally found in food from plants in sexually compatible populations in the past 50 years, despite the hundreds of food plant varieties from sexually compatible plant populations going onto the market each year (Ref. 8), supports a conclusion that the probability of risk is low even for the few substances discussed in this Unit. As an added protection, EPA has placed a condition limiting the exemption to residues present in food from the plants at levels that are not injurious or deleterious to human health.

3. *Relationship of studies to humans.* EPA considered the available information concerning the relationship to human risk of this information on residues in food of plant-incorporated protectants derived through conventional breeding from sexually compatible plants. The effect of these residues on humans was assessed in light of the long history of human

consumption of food derived from plants, and from products such as meat and milk from animals that consume forage and other crops (e.g., corn and other grains), containing residues that are the subject of this exemption, and associated epidemiological studies, nutritional assessments with human volunteers and animal model testing (Refs. 8, 11, 12, 13, 14, 15, 16, 17, 18, and 19). The epidemiological studies and nutritional assessments performed with human volunteers supply data generated on humans and, thus, directly applicable to humans. Information from animal model testing as well as information from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry (including studies on the constituents of food) and plant breeding were also used to predict effects on humans. Because information on human consumption of food derived from plants comprising sexually compatible populations was available and adequately addressed the issues of hazard and exposure for residues that are the subject of this exemption, the Agency relied primarily on the epidemiological and other information generated directly from humans rather than relying on data generated in the laboratory through animal testing.

4. *Dietary consumption patterns*. EPA considered the available information on the varying dietary consumption patterns of consumers and major identifiable consumer subgroups as it pertains to residues that are the subject of this exemption. The consumption of food from plants is part of a balanced and varied diet (Ref. 33). Humans have been consuming food containing substances that may be residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants and thus, all consumers, and all major identifiable consumer subgroups, are, and have been, exposed to the substances that are the subject of this exemption. It is not anticipated that publication of this exemption from the requirement of a tolerance will affect current consumption patterns of food from crop plants by consumers or major identifiable consumer subgroups, and thus no differences in exposure patterns are anticipated.

5. *Available information concerning cumulative effects of the pesticide chemical residue and other substances that have a common mechanism of toxicity.* EPA examined available information on the cumulative effect of residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants, as well as other substances present in food that may have a common mechanism of toxicity with such residues.

i. *What information is available on the cumulative effects of the residues that are the subject of this exemption?* A large amount of information exists for the residues that are the subject of this exemption. The extensive information described in Unit IX.A. and Unit IX.B.1., e.g., epidemiological studies, nutritional assessment studies and animal model testing (Refs. 11, 12, 13, 14, 15, 16, 17, 18, and 19) indicates a very low probability of harm. The few substances occurring naturally in food from plants that EPA has identified as being problematic are discussed in Unit IX.B.2. A discussion of the variation in the levels of substances that may be pesticide chemical residues and may occur naturally among the plants of a sexually compatible population, and the potential consequences of that variation are discussed in Unit IX.B.6.

If information becomes available that indicates its analysis of cumulative effects in Unit IX.B.5., is no longer consistent with the FFDCA exemption standard for residues of a pesticidal substance in this category, EPA will consider the validity of the new information and may act to amend this tolerance exemption.

ii. *Are there substances that occur naturally in food that may share a common mechanism of toxicity with residues that are the subject of this exemption?* Because of the conditions of this exemption, i.e., the genetic material leading to the production of the plant-incorporated protectant is derived through conventional breeding from plants sexually compatible with the recipient plant, the potential for new dietary exposures is low. Thus, EPA considered the effects of all the substances in food from plants when it addressed the safety of food from plants in sexually compatible populations, including those that occur naturally in plants along with the substances that are the subject of this exemption. Food from plants has hundreds of thousands of constituents, and EPA cannot rule out the possibility that in the foods humans consume, common mechanisms of action might exist between some of these substances and the various residues that are the subject of this exemption. For example, the word ''solanine'' generically refers to a group of related steroid glycoalkaloids that naturally occur in plants in the nightshade family such as potatoes, eggplant, peppers and green tomatoes. EPA's analysis considered the effects of these substances in food from plants cumulatively when it addressed the safety of food from plants in sexually compatible populations.

Food from plants in sexually compatible populations is being safely consumed by humans either directly, or indirectly in products such as meat and milk that are derived from animals that consume forage and other crops (e.g., corn and other grains). The history of safe consumption and the information base described in Unit IX.A. and Unit IX.B.1. indicates that any cumulative effects between substances in food that may have a common mechanism with residues that are the subject of this exemption present a very low probability of harm. The analysis made in this preamble in Unit IX.B.6., concerning potential increases in levels of residues apply equally to constituents of food that may have a common mechanism of action with residues that are the subject of this exemption. Variations in the levels of these substances are not expected to be any different than those currently observed in conventional breeding. Experience has shown that food from crop plants in sexually compatible populations is safe for human consumption and/or appropriate processing procedures are widely known and routinely used by processors and consumers in preparing food from such sources. Should EPA in the future identify substances with a common mechanism of toxicity with the residues that are the subject of this exemption, both FIFRA and the FFDCA give the Agency adequate authority to take appropriate action to address any risks these substances may present to human health. Should substances in food that may share a common mechanism of toxicity with residues that are the subject of this exemption present cumulative effects resulting in food safety concerns, the condition limiting this exemption at 40 CFR 174.479 and the requirement to report adverse effects at § 174.71 will provide a mechanism to monitor the effects of this class of products and allow the EPA and FDA to act expeditiously.

iii. *Are there substances that do not occur naturally in food that may share a common mechanism of toxicity with residues that are the subject of this exemption?* EPA examined two groups of substances to determine whether these substances have a common mechanism of toxicity with residues that could be the subject of this exemption.

a. *Do the organophophate and carbamate pesticides have a common mechanism of toxicity with the naturally occurring toxicants solanine?* EPA examined certain of the

organophosphate and carbamate pesticides and the naturally-occurring toxicants, solanine (described in Unit IX.B.2.). EPA examined these substances because many members of these two classes of pesticides inhibit the cholinesterase enzymes (Refs. 30 and 34), and some *in vitro* and intraperitoneal and intravenous injection studies have shown that some of the glycoalkaloids comprising the solanines also can inhibit these enzymes (Refs. 22 and 30). The solanines have also been shown to disrupt cell membranes (Ref. 30).

EPA examined available information generated both *in vitro* and through *in vivo* animal studies on solanine. EPA gave greater weight in its analysis to information generated by animal studies where the animals were exposed through oral ingestion, as such studies are far more likely to provide physiologically significant information. Animal studies performed with the solanines administered to the animals in similar manner that plant-incorporated protectants would be presented in the diet (i.e., through ingestion) show that death could not be attributed to cholinesterase inhibition and its neurotoxic consequences but was due to severe gastrointestinal necrosis from cell membrane disruption (Ref. 35).

Given this information, EPA has concluded that available information is insufficient to create a presumption of the existence of a common mechanism of toxicity between solanine and the organophosphate and carbamate pesticides (Ref. 36), particularly as animal studies suggest the solanines, when used as plant-incorporated protectants, lead to the endpoint of death through membrane disruption.

b. *Do microorganisms have metabolic pathways in common with plants?* One commenter, in response to the May 16, 1997, supplemental document, suggested that some microorganisms may have some metabolic pathways in common with plants, although the commenter was of the opinion that this is not likely to be problematic. EPA agrees that this route of exposure to any substances that may be related to residues that are the subject of this exemption is unlikely to be problematic, and notes that possession of the same metabolic pathways does not equate to expression of the same characteristics. Raw plant foods commonly contain hundreds to several million microorganisms per gram (Ref. 8). Some of these microorganisms are commensals of the plant, others come from the natural environment of the plant (e.g., soil, water, air, other plants). Such microorganisms are routinely consumed with raw agricultural produce. Certain microorganisms are deliberately consumed routinely in high numbers by humans with no ill effects (e.g., Marmite based on a yeast, natto based on the bacterium *Bacillus* subtilis, yogurt made with bacteria of the genus *Lactobacillus*, cheese made with the fungus *Penicillium roquefortii*). This base of experience with actual human consumption indicates that should such microbes have any metabolic pathways in common with foodstuffs from plants, the cumulative effect of substances from these pathways with residues that are the subject of this exemption, presents a very low probability of harm.

c. *Are there any other substances?* EPA cannot rule out the possibility that there may be other substances outside of the food supply that may have a common mechanism of toxicity with the residues that are the subject of this exemption, although it is not aware of any other such substances. Should EPA in future identify substances with a common mechanism of toxicity other than those found in food plants, both FIFRA and the FFDCA give the Agency adequate authority to take appropriate action.

6. *Aggregate exposures of consumers including non-occupational exposures.* EPA considered the available information on the aggregate exposure level of consumers to the residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants, including exposure to these substances in plants when they are not intended to be used as plant-incorporated protectants (i.e., when humans are not intending to use the substance for a pesticidal purpose). This evaluation included a consideration of exposures from dietary sources as well as from other non-occupational sources. Plant-incorporated protectants and their residues are likely to present a limited exposure to humans. In most cases, the predominant, if not the only, exposure route will be dietary. Exposure through other routes is likely to be negligible because the substances are in the plant tissue and thus are found either within the plant or in close proximity to the plant.

In addition, the substances evolved by populations of sexually compatible plants are part of the metabolic cycles of these plants. These substances are biotic and are subject to the processes of biodegradation and decay that all biotic materials undergo (Ref. 37). Biotic materials are broken down to constituent parts through the enzymatic processes of living organisms, and these constituent parts used as the building blocks to make other biotic substances.

Because of their biodegradable nature, the residues that are the subject of this exemption do not bioaccumulate (bioaccumulation occurs when a substance is taken into the body through processes such as eating, and as the body is unable to either break the substance down or eliminate it, the substance accumulates in the tissues) or biomagnify in the tissues of living organisms (biomagnification occurs when a substance bioaccumulates in the bodies of organisms lower in the food chain, and as predators higher in the food chain consume organisms lower in the food chain, more and more of the substance accumulates in the bodies of organisms higher in the food chain) as do such long-lived persistent substances such as DDT (Ref. 38). Humans ingesting the substances that are the subject of this exemption are likely to quickly degrade them and use their constituent elements as nutrients. Because of these characteristics, the potential for exposures to the residues to occur, beyond direct physical exposure to, or consumption of, the plant, is limited. This also contributes to EPA's conclusion that non-dietary exposure (i.e., non-food oral, dermal and inhalation) in non-occupational settings is likely to be negligible.

i. *Dietary exposures?* As described in Unit IX.A. and Unit IX.B.1., a large base of experience exists, including information on human dietary exposure, for the residues exempted by this action. Moreover, dietary exposures other than those for which a large base of information exists, are unlikely to result from this exemption for residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants. Plants in a sexually compatible population are likely to have similar genetic information and have many traits in common. Generations of directed breeding to produce improved crops for cultivation have tended to increase the relatedness, and reduce the genetic variability, of populations of agricultural crop plants (Ref. 6). Sexually compatible plants share a common pool of genetic material, and movement of genetic material encoding pesticidal substances between plants in a sexually compatible population through conventional breeding is unlikely to result in exposure of humans consuming food from such plants to residues to which no humans previously has been exposed and to which the information base underlying this exemption cannot be applied. The SAP Subpanel and the BSAC

Subcommittee at the joint meeting held on January 21, 1994, supported this conclusion and noted that genetic mapping of the genomes of both wild and crop plants reinforce the thesis that plants in sexually compatible populations are likely to possess similar genetic information (Ref. 6). It is likely that substances that are the subject of this exemption are present at low concentrations in the edible parts of plants, and that such substances have long been part of the human diet. There is no evidence at present in the many studies performed on the relationship of diet to health that food from plants in sexually compatible populations, properly handled, has any significant adverse health effect (Refs. 8, 11, 12, 13, 14, 15, 16, 17, 18, and 19).

The primary exposure consideration associated with the substances that are the subject of this exemption is whether the substances, identified in Unit IX.B.2. as toxic at higher concentrations, are likely to be present in food from plants in sexually compatible populations at such concentrations. EPA carefully examined whether there are variations, within and among food plant varieties in sexually compatible plant populations, in levels of plant-incorporated protectants and thus in the residues that are the subject of this exemption from the FFDCA requirement of a tolerance (Ref. 20). The amount of any substance produced by plants normally varies among members of a sexually compatible plant population because of the effects of conditions such as genetic constitution and environment (e.g., weather) (Refs. 8 and 20). Indeed, such variation is observed among plants of the same variety. For example, one researcher (Ref. 8) has shown a 20-fold variation in the amount of ascorbic acid (3 to 61 mg/100g tissue) in different varieties of muskmelon. Because such variation is ubiquitous in populations, differences in the levels of exposure to substances in plants are likely when humans consume food from plants, including differences in exposure to residues that are the subject of this exemption. Such variation is a natural phenomenon common to all plants, however, in controlled food production the variation in the substances identified in Unit IX.B.2. is limited (Ref. 22).

EPA also examined whether the levels of substances any variety within a sexually compatible population could produce are likely to exceed the range of low concentrations found in crop plant varieties safely consumed. For the following reasons, the Agency concluded that such occurrences were unlikely. First, there are several constraints on the extent to which expression of any substance can be increased in highly managed food crop plants without unwanted effects on other, desirable characteristics of the plant such as yield or palatability. In general, breeders balance a number of characteristics (e.g., yield, palatability, height, uniformity of seed drop) in developing marketable plant varieties. Solanine and cucurbitacin, for example, affect palatability as they taste bitter to humans.

Moreover, in conventional breeding, plant breeders assess the new cultivar for food safety, based in part on knowledge of and familiarity with the characteristics of agricultural plants in sexually compatible populations (Ref. 22). EPA's assessment of the likelihood of breeders ensuring that plants developed through conventional breeding will continue to be safe for consumption is supported by the record of safety of the food products from plants in sexually compatible populations. Although hundreds of new varieties come on the market each year, within the past 50 years, conventional plant breeding of plants in sexually compatible populations has recorded very few instances of plant varieties causing food safety problems. The two identified instances (Ref. 8), high psoralen expressing celery that in the 1980s caused dermatitis in grocery employees and the Lenape potato in the late 1960s with increased glycoalkaloid levels, involved increases in the level of known toxicants (which may or may not be plant-incorporated protectants depending on whether humans intend to use these substances for preventing, destroying, repelling or mitigating any pest). In both cases, the problem was identified and the appropriate measures taken to protect the public health. In the case of the Lenape potato, food processors in routine screening detected the high levels of solanine and the potatoes were removed from the market before exposure of consumers (Ref. 8). In contrast to these few problematic occurrences, there are many studies indicating the health benefits of consuming plant foods that likely contain residues that are the subject of this exemption (Refs. 8, 11, 12, 13, 14, 15, 16, 17, 18, and 19).

A second exposure consideration is whether this exemption will affect the ability of individuals with food sensitivities to manage these sensitivities. To protect themselves, individuals with food sensitivities generally avoid the food, and related foods, that cause them problems (Ref. 39). This exemption will not affect the efficacy of this strategy of avoidance, because the exemption will not affect the ability of individuals to recognize and avoid foods that cause them problems (Refs. 27, 39, and 40). For example, the ability of persons who have the Mediterranean form of the inherited G6PD deficiency to deal with their disease by avoiding (i.e., not consuming) fava beans or foods made with fava beans will not be affected. The substances in fava beans that can cause hemolytic anemias in such persons will be exempt only if they are moved through conventional breeding among fava bean plants and plant varieties sexually compatible with fava beans; a population of plants in which such substances normally occur, and the food of which individuals with the inherited G6PD deficiency avoid (Ref. 27). Similarly, the efficacy of the strategy of avoidance will not be affected for individuals suffering from food allergy (Ref. 39) or enteropathies such as celiac disease (gluten-sensitive enteropathy) (Ref. 40). Moreover, the efficacy of the monitoring, processing, and preparation methodology which humans are familiar with and have been adequate in the past to produce food safe for consumption will not be affected by publication of the exemption, e.g., the monitoring procedures for solanine used in the breeding and marketing of potatoes.

EPA believes the history of familiarity with agricultural plants in sexually compatible populations, and thus with the likely progeny of genetic exchanges between plants in such populations (Ref. 8), and the procedures currently employed in plant breeding to screen out undesirable traits in such populations, support a tolerance exemption for residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants. However, to ensure that the Agency can act expeditiously should any rare instances of risk arise, EPA is placing at 40 CFR 174.479 a condition on this exemption from the requirement of a tolerance limiting the concentrations in food of substances such as toxicants that may be injurious or deleterious to human health. EPA is also implementing an adverse effects reporting requirement at § 174.71 that will serve to alert the Agency to any such rare instances of risk.

One comment received in response to the May 16, 1997, supplemental document (62 FR 27132), suggested that plant extracts might be used in some pharmaceutical preparations. The commenter did not provide any examples of these types of situations, nor any information on such extracts. Without such additional information, it

is difficult to determine whether the extracts would contain substances related to residues that are the subject of this exemption. However, even if such related substances are present in some pharmaceutical preparations, on a per person basis, the potential amounts involved in these exposures are likely to be a negligible contribution to aggregate exposure. The commenter also was of the opinion that such uses are not likely to be problematic.

ii. *Dermal exposure*. With regard to the dermal route of exposure, residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants may in some cases be present in sap or other exudates from the plant or the food 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 substances on a non-occupational basis. Although contact dermatitis can occur from such exposure (Refs. 41 and 42), these reactions are generally mild, of a self-limiting nature or self-diagnosed and treated.

Most of the substances that could be the subject of this exemption are unlikely to pass through the skin to affect other organ systems (Refs. 41, 42, and 43). For those substances which possess to some degree properties that allow some penetration of the skin, the potential amounts of such exposures, on a per person basis, are likely to be a negligible contribution to aggregate exposure, or do not present adverse effects.

There are a few substances with the ability to present an effect on dermal exposure on a non-occupation basis, that might be residues of plant-incorporated protectants, if humans intend to use these substances as pesticides. For example, one substance present in a food (condiment) Americans might use in preparing meals and identified as a potential skin irritant (Refs. 8 and 22) is the phenolic, capsaicin, found in cayenne pepper. Capsaicin is used medically in a topically applied cream, which facilitates passage of the capsaicin across the barrier of the outer layer of the skin, at concentrations of 0.025 to 0.075% capsaicin. The cream is applied up to four times daily for pain control and treatment of psoriasis (Refs. 22 and 44). Cayenne pepper can be used liberally in the diet. Currently, cayenne pepper is exempt from the requirement of tolerance when it is used on food crops (40 CFR 180.1165). Acute toxicity through the oral route has been examined in several animal species, and it is estimated that the lethal dietary dose for a 150 pound individual is 2.2 kilograms (Refs. 22 and 45). Given the low toxicity of capsaicin, even if capsaicin should penetrate through the barrier of the skin, aggregate exposure through the dermal and dietary routes is not anticipated to present harm.

A second substance examined because of known effects beyond mild dermatitis with dermal exposure are the psoralens. These substances occur naturally in a wide range of plants but occur in the highest concentrations in celery, dill and parsley (Refs. 22 and 41). Psoralens can be phototoxic to the skin in conjunction with sunlight (UV light). Due to their relative solubility in oils, psoralens can penetrate into the skin cells, where they intercalate into the genetic material of the skin cell (Refs. 22 and 41). Subsequent exposure to sunlight (UV light) causes the genetic material to ''cross link,'' affecting the ability of the cell to further process its genetic material. This may result in skin blisters and rashes. This UV-dependent phototoxicity has also been implicated in mutations that may lead to skin cancer (Refs. 22 and 41). In spite of the potential for this type of adverse effect with the psoralens, there are few reported incidents for substances derived through conventional breeding from sexually compatible plants (Ref. 8).

Psoralens (supervised and in small doses) are also used in the treatment of a variety of skin diseases, including vitiligo and psoriasis (Ref. 22), primarily through topical application.

The primary route through which humans in general are exposed to psoralens is dietary, and the psoralens are not toxic when ingested. Given the low oral toxicity, the supervised use of psoralen in medicine, the low concentrations of psoralen in celery, dill and parsley currently on the market, and the condition EPA has placed on this exemption limiting the amount of substances in food that may have an injurious or deleterious effect on human health, EPA finds that for psoralen, were this substance to be used as a plant-incorporated protectants derived through conventional breeding from sexually compatible plants, there is a reasonable certainty that no harm will result from aggregate exposure.

Those few substances from food plants discussed in Unit IX.B.2., which might be present in foods Americans might use in preparing meals and which at higher concentrations can cause adverse effects, do so when ingested (Refs. 22, 26, 29, and 31). Substances that are the subject of this exemption are unlikely to pass through the skin to affect target organs. For those substances which possess to some degree properties that allow some penetration of the skin, the potential amounts of such exposures, on a per person basis, are likely to be negligible in comparison to potential exposure through the dietary route, or do not cause adverse effects. Dermal exposures are, thus, unlikely to contribute significantly to aggregate exposure.

One comment received in response to the May 16, 1997, supplemental document (62 FR 27132) suggested that plant extracts might be used in some cosmetic preparations. The commenter was of the opinion that such uses are not likely to be problematic. The commenter did not provide any examples of these types of extracts, nor any information on the source or composition of such extracts. Without such additional information, it is difficult to determine whether the extracts would contain substances related to residues that are the subject of this exemption. EPA is aware that some floral extracts are used in perfumes, e.g., lavender, jasmine, rose. However, lavender, jasmine and rose are not generally consumed as staple foods, although parts of these plants can be brewed into teas or tisane. The amounts ingested through the tisane or by passing through the skin from perfumes is likely to be very small. Further, EPA is not aware of any reports of adverse effects from use of these flowers in tisane or perfumes. Even if such substances are present in some cosmetic preparations, on a per person basis, the potential amounts involved in these exposures are likely to be negligible.

EPA is also aware of other extracts used in perfumes from plants consumed as food, e.g., carrot, fennel, garlic, lemon. Even if such substances are present in some cosmetic preparations, on a per person basis, the potential amounts involved in these exposures are likely to be a negligible contribution to potential exposure through the dietary route.

iii. *Inhalation exposure*. With regard to exposure through inhalation, residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants may in some cases be present in pollen and some individuals (e.g., those living or working near enough to farms, nurseries or other plant-growing areas to be exposed towind-blown pollen, or visiting such areas) may be exposed, through inhalation, to the pollen. On a per person basis, the potential amounts of pollen involved in these exposures are likely to be negligible in comparison

to potential exposure through the dietary route. Residues of the pesticidal substance will not in every case be present in the pollen. When present in pollen, the residues are likely to be integrated into the tissue of the pollen grain. Pollen grains are solid, insoluble particles of sufficiently large diameter that they are filtered out in the nasopharynx or in the upper respiratory tract (Refs. 41 and 46). This exemption will not change current exposures nor affect strategies for dealing with residues that are the subject of the exemption. (Ref. 41).

iv. *Drinking water*. EPA also evaluated potential non-occupational exposures in drinking water. The substances in plants or parts of plants, including residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants, are produced and used inside the living plant itself. The residues are part of the living tissue of the plant. 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 tissue (including any residues that are the subject of this exemption in the tissue) as building blocks for making their own cellular components or for fueling their own metabolisms. The residues that EPA is exempting in this action, including those identified at Unit IX.B.2., as toxic at higher concentrations, are subject to the same processes of biodegradation and decay that all biotic materials undergo. This turnover of biotic materials in nature through a process of biodegradation occurs fairly rapidly (Ref. 37). There is no indication that naturally-occurring plant biotic materials, including the residues that are the subject of this exemption, are resistant to biodegradation. Because of the fairly rapid turnover of these residues, even if they reach surface waters (through pollen dispersal or parts of the plants (leaves, fruits etc.) falling into bodies of water), they are unlikely to present anything other than a negligible exposure in drinking water drawn either from surface or ground water sources.

v. *Residential exposure*. EPA is not aware of any residential uses of plant-incorporated protectants that might result in exposure to residues that are the subject of this exemption.

7. *Sensitivities of subgroups*. EPA considered available information on the sensitivities of subgroups as it pertains to residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants. In performing its assessment, the Agency considered that the diet includes all of the food items that are customarily eaten by human populations or subpopulations. As discussed in this preamble, this exemption will not affect the current pattern of exposure to residues that are the subject of this exemption. Individuals recognize and are familiar with the plant-derived food they consume, and, based on prior experience with food, individuals avoid consuming foods containing substances they know, either through personal experience or through acquired knowledge, cause them problems (Refs. 8, 39, and 40). Because the exposure pattern will not be affected by publication of this exemption, the efficacy of the current strategy whereby sensitive individuals recognize and avoid foods known to cause them problems will not be affected by this exemption (Ref. 39, 40). For example, the ability of persons who have the Mediterranean form of the inherited G6PD deficiency to deal with their disease by avoiding (i.e., not consuming) fava beans will not be affected. Thus, no subgroup should be adversely affected by the exemption.

8. *Estrogenic or other endocrine effects*. While there is some information on estrogenic effects from exposure to certain pesticides, the data are limited. It is known that certain food plants (e.g., soybeans) contain estrogen mimics, termed phytoestrogens. Such phytoestrogens are currently being consumed by humans in food derived from plants and are part of the extensive history of safe human consumption of food from plants. Although no information was submitted to EPA on this issue despite the Agency specifically soliciting it in the May 16, 1997, supplemental document (62 FR 27132), EPA cannot rule out the possibility that such phytoestrogens could be used as plant-incorporated protectants. Potential exposure of humans via consumption of plant tissue to phytoestrogens exerting estrogenic effects and used as plant-incorporated protectants may need to be considered as EPA examines the issue of endocrine disruptors. If dietary exposure to phytoestrogens (that are also plant-incorporated protectants) is discovered to be a significant factor, the Agency will re-examine this exemption from the requirement of a tolerance in light of that information.

9. *Safety factors*. EPA did not rely solely on available animal data in reaching its determination that residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants can be exempted from the requirement of a tolerance. There is a long history of safe human consumption of food containing residues that are the subject of this exemption, and of food derived from animals that consume forage and other crops containing these residues (e.g., corn and other grains). EPA thus was able to rely on epidemiological studies on humans, nutritional assessments with human volunteers and animal model testing generated through a century of systematic scientific study and available in the public literature (Refs. 8, 11, 12, 13, 14, 15, 16, 17, 18, and 19). EPA also relied on knowledge from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry (including studies on plant constituents) and plant breeding. EPA believes that long-term evidence of human consumption and the large base of scientific data generated by epidemiological studies on humans and nutritional assessments with human volunteers, with a more limited reliance on animal experimentation data, is the appropriate information for evaluating whether residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants warrant exemption. Because EPA was able to rely on data from humans, the Agency concluded that a safety factor designed to account for uncertainties in extrapolating from animal data would not be necessary. In addition, because the available epidemiological and other information generated on humans was based on studies employing very large numbers of individuals, the Agency concluded that a ten-fold safety factor to account for uncertainties in analyzing the human data would not be necessary.

10. *Infants and children*. EPA considered available information on consumption patterns of infants and children, including special sensitivity, cumulative effects of residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants with other substances that may have a common mechanism of toxicity with these residues, and the need for a margin of safety for infants and children.

i. *Dietary consumption patterns*. EPA considered available information on the dietary consumption pattern of infants and children as pertains to residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants. 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 milk products for nutrition, although some infants are fed

soy-based products. Soy-based products may contain residues that are the subject of this exemption. Infants begin as early as four months of age to consume specific types of solid foods from plants that may contain residues that are the subject of this exemption. Subsequent to four months of age, apart from processing to facilitate swallowing, the diets of infants begin to be based on foods consumed by the general adult population albeit in different proportions. 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 changes to more closely resemble an adult diet. The substances that are the subject of this exemption occur in the normal diet. They have been consumed by infants and children over very long periods of time and currently are being consumed by infants and children. Exposure as part of a normal diet to these substances is highly unlikely to lead to harm to infants and children. As the diets of humans change from infancy through childhood and into adulthood, there is some possibility that the amount of the substances that are the subject of this exemption being consumed may change with those consuming the greatest amounts of food of plant origin receiving the highest exposure to substances that are the subject of this exemption. There is no evidence that such changes are likely to result in disproportionately high consumption of these residues in comparison to the general population. The evidence strongly suggests that consumption of foods containing the substances that are the subject of this exemption, 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, is highly unlikely to lead to any harm.

ii. *Special susceptibility*. EPA considered available information on the potential for special susceptibility of infants and children, including prenatal and postnatal toxicity, to residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants. The substances that are the subject of this exemption occur in the normal diet, and there is no evidence that exposure to such residues, as components of food, present a different level of dietary risk for infants and children, in light of neurological differences between infants and children and adults, than they would present for the adult population.

iii. *Cumulative effects of residues with other substances with a common mechanism of toxicity*. EPA examined the available information on the cumulative effect of residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants as well as other substances in food that may have a common mechanism of toxicity with these residues. The Agency's consideration of the effects of the residues that are the subject of this exemption, and other substances that have a common mechanism of toxicity, in Unit IX.B.5. and Unit IX.B.6., included consideration of effects on infants and children.

iv. *Margin of safety*. In determining whether the residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants are safe, FFDCA section 408(b)(2)(C) directs EPA in the case of threshold effects to apply a tenfold margin of safety for the residues and other sources of exposure to infants and children to account for potential prenatal and postnatal toxicity and completeness of data effects with respect to exposure and toxicity to infants and children, unless a different margin will be safe (21 U.S.C. 346a(b)(2)(C)). For residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants, EPA has determined that a tenfold margin of safety is not necessary to protect infants and children. EPA reaches this determination based on valid, complete and reliable information. EPA based its assessment of exposure and toxicity upon the information base described in Unit IX.A. and Unit IX.B.1. (Refs. 8, 11, 12, 13, 14, 15, 16, 17, 18, and 19) that arose through the long history of human consumption of food containing substances which are the subject of this exemption, and other animals that consume plants containing these substances, and other substances in food that may have a common mechanism of toxicity (Ref. 8). EPA also relied upon knowledge from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry (including the constituents of food) and plant breeding. Based on all of this information, EPA concludes that it is unlikely that consumption of food containing residues that are the subject of this exemption, 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, would lead to any harm. Thus, EPA has concluded that consumption of food containing residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants is safe for infants and children, and that a margin of safety need not be applied for these residues in food.

11. *Analytical methods*. EPA has decided that there is no need to employ a practical method for detecting and measuring the levels of most of the substances in plants that might be used as plant-incorporated protectants and thus might be residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants. It is not anticipated that these substances would cause adverse effects. EPA has identified nine substances of plant origin that are found in plants that are part of the normal American diet and if present at high levels can present toxic effects. These are discussed in Unit IX.B.2. Practical methods exist for detecting and measuring the concentration of these substances in food (Ref. 22). EPA consulted with the Department of Health and Human Services (DHHS) in developing the proposed exemption and in issuing this final rule.

C. Determination of Safety for United States Population, and Infants and Children

Based on the information discussed in this document today and that discussed in the 1994 **Federal Register** documents and the supplemental documents and the associated record as described in Unit X., EPA concludes that there is a reasonable certainty that no harm will result to the United States population in general, and infants and children in the United States, from aggregate exposure to any residues of the pesticidal substance portion, or inert ingredients, of plant-incorporated protectants derived through conventional breeding from plants sexually compatible with the recipient plant, including all anticipated dietary exposures and all other exposures for which there is reliable information. This finding is based on extensive use and experience, and the large associated literature on epidemiological studies, nutritional assessments with human volunteers and animal model testing of foods from plant varieties developed by moving traits among plants in sexually compatible populations. This information shows that adverse effects due to aggregate exposure through the dietary, non-food oral, dermal and inhalation routes are highly unlikely for pesticidal substances, or inert ingredients, derived through

conventional breeding from plants sexually compatible with the recipient plant. And in the unlikely event such adverse effects do occur, EPA has implemented mechanisms to ensure that it will be notified, and that FDA will be able to seize the adulterated food; i.e., the adverse effects reporting requirement at 40 CFR 174.71 and the condition limiting this exemption at § 174.479.

X. Documents in the Official Record

As indicated in Unit I.B.2., the official record for this rule has been established under docket control number OPP–300368B, the public version of which is available for inspection as specified in Unit I.B.2.

A. References

The following books, articles and reports were used in preparing this final rule and were cited in this document by the number indicated:

1. Whittaker, R. H. 1969. New concepts of kingdoms of organisms. Science, 163:150–160.

2. Environmental Protection Agency. 2000. Summary of public comments and EPA responses on issues associated with plant-incorporated protectants (formerly plant-pesticides) for docket OPP–300368 and OPP–300368A.

3. Hanson, M., and J. Halloran. In a letter dated February 22, 1995 on dockets OPP–300367 through OPP–300371.

4. Goldburg, R. In a letter dated February 6, 1995 on dockets OPP–300367 through OPP–300371.

5. Rissler, J., and M. Mellon. In a letter dated January 23, 1995 on dockets OPP–300367 through OPP–300371.

6. Environmental Protection Agency. 1994. Joint meeting of the FIFRA Scientific Advisory Panel (SAP); Subpanel on plant-pesticides, and the EPA Biotechnology Science Advisory Committee (BSAC); Subcommittee on plant-pesticides. January 21, 1994. Final Report.

7. Raven, P. H., R. F. Evert, and S. E. Eichhorn. 1992. Biology of Plants. Fifth Edition. Worth Publishers, New York, New York.

8. International Food Biotechnology Council. 1990. Biotechnologies and food; Assuring the safety of foods produced by genetic modification. In: Regulatory Toxicology and Pharmacology. Vol 12. Academic Press, New York, New York.

9. Wilks, H. M., A. Cortes, D. C. Emery, D. J. Halsall, A. R. Clarke and J. J. Holbrook. 1992. Opportunities and limits in creating new enzymes. In: Enzyme Engineering XI. Edited by D. S. Clark and D. A. Estell. Annals of the New York Academy of Sciences. Vol. 672. The New York Academy of Sciences. New York, New York.

10. Environmental Protection Agency. Meeting of the EPA Biotechnology Science Advisory Committee (BSAC); Subcommittee on plant-pesticides. July 13, 1993. Final Report.

11. World Cancer Research Fund and American Institute for Cancer Research. 1997. Food, Nutrition and the Prevention of Cancer: A Global Perspective. BANTA Book Group, Menasha, Wisconsin.

12. Lampe, J. M. 1999. Health effects of vegetables and fruit: assessing mechanisms of action in human experimental studies. *American Journal of Clinical Nutrition*. Sep;70(3 Suppl):475S–490S.

13. Ogomoto, I. A. Shibata and K. Fukuda. 2000. World Cancer ResearchFund/American Institute of Cancer Research 1997 recommendation: applicability to digestive tract cancer in Japan. Cancer Causes Control Jan;11(1):9–23.

14. Joseph, J. A., B. Shukitt-Hale, N. A. Denisova, D. Bielinski, A. Martin, J. J. McEwen and P. C. Bickford. 1999. Reversals of age-related declines in neuronal signal transduction, cognitive, and motor behavioral deficits with blueberry, spinach, or strawberry dietary supplementation.*Journal of Neuroscience.* Sep 15;19(18):8114–21.

15. Segasothy, M. and P. A. Phillips. 1999. Vegetarian diet: panacea for modern lifestyle diseases? *QJM Monthly Journal of the Association of Physicians*. Sep;92(9):531–44.

16. Joshipura, K. J., A. Ascherio, J. E. Manson, M. J. Stampfer, E. B. Rimm, F. E. Speizer, C. H. Hennekens, D. Spiegelman and W. C. Willett. 1999. Fruit and vegetable intake in relation to risk of ischemic stroke. *Journal of the American Medical Association*. Oct6;282(13)1233–9.

17. Thompson, H. J., J. Heimendinger, A. Haegele, S. M. Sedlacek, C. Gillette, C. O'Neill, P. Wolfe and C. Conry. 1999. Effect of increased vegetable and fruit consumption on markers of oxidative cellular damage. *Carcinogenesis*. Dec;20(12):2261–6.

18. New, S. A., S. P. Robins, M. K. Campbell, J. C. Martin, M. J. Garton, C. Boltin-Smith, D. A. Grubb, S. J. Lee and D. M. Reid. 2000. Dietary influences on bone mass and bone metabolism: further evidence of a positive link between fruit and vegetable consumption and bone health?*American Journal of Clinical Nutrition*. Jan;71(1):142–51.

19. Michaud, D. S., D. Spiegelman, S. K. Clinton, E. B. Rimm, W. C. Willett and E. L. Giovannucci. 1999. Fruit and vegetable intake and incidence of bladder cancer in a male prospective cohort. *Journal of the National Cancer Institute*. Apr7;91(7):605–13.

20. Environmental Protection Agency issue paper. 1994. FIFRA: Benefit and environmental risk considerations for inherent plant-pesticides.

21. Agrios, George. 1988. Plant Pathology. Third Edition. Academic Press. New York, New York.

22. Environmental Protection Agency issue paper. 2000. Natural toxicants in food.

23. USDA Agricultural Research Service Poisonous Plant Research Laboratory. Bulletin 415: Poisonous plants of the western United States: Neurotoxic and mycotoxic plants. [http://www.pprl.usu.edu/bulletin.htm]

24. Hernando, J. E. and J. Leon (eds) Neglected Crops: 1492 from a different perspective. FAO Plant production and protection series No. 26. Rome Italy, p. 131–148. 1994.

25. Shibamoto, T. And L.F. Bjeldanes. 1993. Introduction to Food Toxicology. Academic Press, Inc. San Diego, New York, Boston.

26. Ellenhorn, M. J. S. Schonwald, G. Ordog and J. Wasserberger. 1997. Ellenhorn's Medical Toxicology: Diagnosis and Treatment of Human Poisoning. Second Edition. Williams and Wilkins. Baltimore, MD

27. Cooper, R. A., and H. F. Bunn. Hemolytic anemias. 1980. In: Harrison's Principles of Internal Medicine. Edited by. K. J. Isselbacher, R. D. Adams, E. Braunwald, R. G. Petersdorf and J. D. Wilson. McGraw-Hill Company.

28. Coulston, F., and A. C. Kolbye. 1990. (Eds) Regulatory Toxicology and Pharmacology. 12(3), S20–S30.

29. Concon, J. M. 1988. Food Toxicology: Principles and Concepts. Marcel Decker Inc. New York and Basel.

30. Environmental Protection Agency issue paper. 2000. The glycoalkaloid class; solanine and chaconine: Mechanisms of action.

31. D'Mello, J. P. F. 1997. Handbook of Plant and Fungal Toxicants. CBC Press. Boca Raton, New York.

32. Tice, R. 1998. Chacoline and solanine: Review of the Toxicological Literature. Prepared for E. Zeiger, National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health. [http://ntp-server.niehs.nih.gov/htd. ...und/ExecSumm/ ChaconineSolanine.html

33. Environmental Protection Agency. 2000. Benefits of fruits and vegetables.

34. Taylor, P. 1996. Anticholinesterase agents. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics. Ninth Edition. Edited by J. G. Hardman, L. E. Limbird,

P. B. Molinoff, and R. W. Rudden. McGraw-Hill Health Profession Division. New York, New York.

35. Baker, D. C., R. F. Keeler, and W. P. Gaffield. 1988. Mechanism of death in syrian hamsters gavaged potato sprout material. Toxicologic Pathology. Vol. 16:333

36. Environmental Protection Agency. 1999. Guidance for identifying pesticide chemicals and other substances that have a common mechanism of toxicity. FAX-on-Demand Number : (202) 401–0527. Item: 6055.

37. Atlas, R. and R. Bartha. 1987. Microbial Ecology. Benjamin/Cummings Publishing Company, Inc. Menlo Park, California.

38. National Research Council. 1999. Hormonally Active Agents in the Environment. National Academy Press. Washington DC.

39. Yunginger, J. W. 1991. Food Antigens. In: Food Allergy: Adverse Reactions to Foods and Food Additives. Edited by D. D. Metcalfe, H. A. Sampson, and R. A. Simon. Blackwell Scientific Publications. Cambridge, Massachusetts.

40. O'Mahony, S. And A. Ferguson. 1991. Gluten-Sensitive Enteropathy (Celiac Disease). In: Food Allergy: Adverse Reactions to Foods and Food Additives. Edited by D. D. Metcalfe, H. A. Sampson, and R. A. Simon. Blackwell Scientific Publications. Cambridge, Massachusetts.

41. Environmental Protection Agency issue paper. 2000. Dermal and inhalation exposure to plant substances.

42. Lovell, C. R. 1993. Plants and the skin. First edition. Oxford, Blackwell Scientific Publications.

43. Guy, R. H., and J. Hadgraft. 1991. Principles of skin permeability relevant to chemical exposure. In: Dermal and Ocular Toxicology: Fundamentals and Methods. Edited by D. W. Hobson. CRC Press Boca Raton, Florida.

44. Murray, M. T. 1995. The Healing Power of Herbs. Prima Publishing, Rocklin, California.

45. Glinsukon, T., Stitmunnaithum, V., Toskulkao, C., Buranawuti, T., and V. Tangkrisanavinont. Acute toxicity of capsaicin in several animal species. *Toxicon*. 18(2):215–20. 1980.

46. Environmental Protection Agency. 1997. Exposure Factors Handbook. Volume 1. National Center for Environmental Assessment. EPA/600/P–95/002Fa.

47. Environmental Protection Agency. 2000. Economic analysis of the plant-incorporated protectant regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

B. Additional Information

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–30069A 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–300371B for the companion 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)'' (FRL–6057–5) published elsewhere in this issue of the **Federal Register**.

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)'' (FRL–6057–7)published elsewhere in this issue of the **Federal Register**.

The docket identified by the docket control number OPP–300368B for this document (FRL–6057–6).

Also include in the complete official public record are:

1. Public comments submitted in response to the proposals and supplemental documents cited in this Unit X.B.

2. Reports of all meetings of the Biotechnology Science Advisory Committee and the FIFRA Science Advisory Panel pertaining to the development of this final rule.

3. The Economic Analysis (EA) for the final rule on FIFRA regulations for plant-incorporated protectants, and documents supporting the EA (Ref. 47).

4. Support documents and reports.

5. Records of all communications between EPA personnel and persons outside EPA pertaining to the final rule. (This does not include any inter-agency and intra-agency memoranda, unless specifically noted in the Indices of the dockets).

6. Published literature that is cited in this document.

7. The response to comments document pertaining to the development of this final rule (Ref. 2).

XI. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408 and does not impose any other regulatory requirements. As such, The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive

Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

This action does not 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), nor does it 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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

This action does not impose any enforceable duty or contain any unfunded mandate, and will not otherwise significantly or uniquely affect small governments as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). This rule does not significantly or uniquely affect the communities of Indian trial governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), do not apply to this rule. Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), which took effect on January 6, 2001, revokes Executive Order 13084 as of that date. EPA developed this rulemaking, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13084. For the same reasons stated for Executive Order 13084, the requirements of Executive Order 13175 do not apply to this rule either. For the same reasons, this rule does not have any substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). This rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The Agency's determination is based on the fact that an exemption from the requirement of a tolerance under FFDCA section 408, such as that contained in this rule, will not adversely affect any small businesses. Additional information about the Agency's determination may be found in the small entity impact analysis prepared as part of the economic analysis for the FIFRA rulemaking, which is available in the public version of the official record under OPP–300368B (Ref. 47). The Agency has also 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 these actions. See 46 FR 24950, May 4, 1981.

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 this action is not expected to affect energy supply, distribution, or use.

XII. Submission to Congress and the Comptroller General

The Congressional Review Act, 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. 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 this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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: July 12, 2001.

Christine T. Whitman,

Administrator.

Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y and 21 U.S.C. 346a and 371.

2. Section 174.479 is added to subpart W to read as follows:

§ 174.479 Pesticidal substance from sexually compatible plant; exemption from the requirement of a tolerance.

Residues of a pesticidal substance that is part of a plant-incorporated protectant from a sexually compatible plant are exempt from the requirement of a tolerance if all the following conditions are met:

(a) The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient food plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.

(c) The residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health.

[FR Doc. 01–17983 Filed 7–16–01; 11:42 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[OPP–300370B; FRL–6760–4]

RIN 2070–AC02

Plant-Incorporated Protectants (Formerly Plant-Pesticides), Supplemental Proposal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Supplemental proposal; notice of data availability.

SUMMARY: EPA solicits additional comment on the exemptions it proposed in 1994 for plant-incorporated protectants. Specifically, EPA solicits comment on two alternative regulatory approaches to plant-incorporated protectants derived from plants sexually compatible with the recipient plant that the Agency is considering in response to comments received on the 1994 proposal. EPA requests comment on the issues raised by commenters in response to EPA's 1994 proposed exemptions for plant-incorporated protectants derived from sexually compatible plants, as well as on any new issues presented by the proposed regulatory alternatives. The Agency is requesting comment on whether a distinction made on the basis of process is appropriate. EPA is also providing notice that it has placed the report issued by the National Academy of Sciences (NAS) entitled ''Genetically Modified Plants: Science and Regulation'' in the dockets for the rulemakings relating to certain proposals on plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). With this supplemental document, EPA has reopened the comment period for these particular 1994 proposals to allow the public an opportunity to comment on the information, analyses, and conclusions in the NAS report pertaining to plant-incorporated protectants that act primarily by affecting the plant or are based on viral coat proteins, as well as on specific questions posed by the Agency.

DATES: Comments, identified by docket control number OPP–300370B, must be received on or before August 20, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–300370B in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Phillip Hutton, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8260; e-mail address: hutton.phil&epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a person or company involved with agricultural biotechnology that may develop and market plant-incorporated protectants. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Pesticide manufacturers	32532	Establishments primarily engaged in the formulation and preparation of agricultural and household pest control chemicals
Seed companies	111	Establishments primarily engaged in growing crops, plants, vines, or trees and their seeds
Colleges, universities, and professional schools	611310	Establishments of higher learning which are engaged in development and marketing of plant-incorporated protectants
Establishments involved in research and development in the life sciences	54171	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 table could also be affected. The North American Industrial Classification System (NAICS) codes are 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 provisions in 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. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–300370B. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well

as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–300370B in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket&epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–300370B. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the proposed rule or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. Statutory Authority

Section 2(u) of FIFRA (7 U.S.C. 136 *et seq.*) 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'' with certain exceptions (7 U.S.C. 136(t)).

The substances plants produce for protection against pests are pesticides under the FIFRA definition of pesticide, if humans intend to use these substances for ''preventing, destroying, repelling or mitigating any pest,'' regardless of whether the pesticidal capability evolved in the plants, or were introduced through traditional breeding or through the techniques of modern genetic engineering (e.g., recombinant DNA (rDNA)). These substances, produced and used in living plants, along with the genetic material necessary to produce them, are called ''plant-incorporated protectants'' by EPA.

FIFRA section 3 provides, with certain limited exceptions, that no person may sell or distribute in the United States, any pesticide that is not registered under the Act (7 U.S.C. 136a (a)). Before a product may be registered as a pesticide under FIFRA, it must be shown that ''when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment'' (7 U.S.C. 136a (c)(5)). A pesticide causes ''unreasonable adverse effects on the environment'' if it causes ''(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 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)).

EPA is authorized to promulgate regulations under section 3(a), ''[t]o the extent necessary to prevent unreasonable adverse effects on the environment, [that] limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act and that is not the subject of an experimental use permit under section 5 or an emergency exemption under section 18'' (7 U.S.C. 136a(a)).

A person may, however, sell and distribute an unregistered pesticide if EPA exempts the pesticide pursuant to FIFRA section 25(b)(2). FIFRA section 25(b)(2) authorizes EPA to exempt, by regulation, any pesticide of a character that is unnecessary to be subject to FIFRA in order to carry out the purposes of the Act (7 U.S.C. 136w(b)(2)).

Section 408 of the 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 a commodity or food primarily as a

result of the metabolism or other degradation of a pesticide chemical'' (21 U.S.C. 321(q)(2)). The 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)).

B. Other Federal Agencies

EPA is the Federal agency primarily responsible for the regulation of pesticides. In fulfilling this mission, 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 the 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 for Regulation of Biotechnology (51 FR 23302, June 26, 1986); 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. It is also more likely to conserve resources as submitters would more likely be able to use data developed for one agency to meet requirements posed by another agency for the same or similar products.

1. *USDA*. USDA has authority to prevent the introduction and dissemination of plant pests under the PPA. Before introducing into the environment a plant that is regulated under either of these statutes, approval must be obtained from the USDA/Animal Plant Health Inspection Service (APHIS) unless the plant is exempt from USDA/APHIS regulation. The USDA regulations use genetic engineering as a criterion for determining the scope of its regulations (Refs. 1, 2, and 3).

EPA recognizes that there is a potential for duplicative oversight with respect to certain issues that may arise in plant-incorporated protectant decisions. For example, some of the plant-incorporated protectants not exempted by EPA are also subject to APHIS/USDA requirements under the PPA. The potential for most plants containing plant-incorporated protectants to pose weediness concerns is directly considered by USDA/APHIS under PPA. 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 when reviews of any plant-incorporated protectant indicates reason for concern over any of these issues. Weediness is generally thought to be due to a multiplicity of factors. The Agencies will work to coordinate their analyses of these factors in accordance with their respective expertise and jurisdiction. EPA's focus in considering these issues is on the statutory determination on unreasonable adverse effects the Agency must make with respect to pesticides, rather than on the engineered plant itself. In particular, these plant-related issues may potentially impact use patterns of pesticides, which are of relevance to the Agency. EPA and USDA/APHIS will work together to avoid potential duplication and inconsistencies.

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 FFDCA and the reorganization that created EPA, pesticides as defined by FIFRA are subject to EPA's regulatory authority under FFDCA. Recently, FDA announced its intent to propose a pre-market notification scheme for foods derived from plants modified through the use of modern biotechnology.

III. Proposed Alternative Regulatory Approaches to Plant-Incorporated Protectants Derived Through Genetic Engineering from Sexually Compatible Plants

In this Unit, EPA describes the two alternative regulatory approaches the Agency is considering to address the issues raised in comment for this class of plant-incorporated protectants. EPA solicits public comment on any new issues presented by the proposed regulatory alternatives as well as on the issues raised in comment on the 1994 proposal. The Agency intends to consider public comments and make final determinations to complete these other rulemakings within 9 to 12 months after the close of the comment period for the supplemental proposal, which is currently set at 30 days. Until the Agency takes a final action on these other exemptions, the Agency intends to maintain its current practices on regulation of plant-incorporated protectants.

A. History

The plant-incorporated protectants that a plant population has evolved, and thus naturally possesses, can be varied, including, for example, structural characteristics of the plant, the production of general metabolites that have toxic properties, biochemical cascades resulting in localized necrosis of plant tissue, or the production of specific toxic substances in response to pest attack. The plant-incorporated protectants that characterize a particular plant population can be shared among the members of the population by the process of sexual hybridization. There is a large base of human experience in selective breeding of plants within sexually compatible populations using conventional hybridization techniques. There is much experience growing such plants, and preparing and consuming food from plants in such populations. Based on this experience and the information base generated through scientific study of such plants and their constituents, and on knowledge in plant genetics, plant physiology, phytopathology, microbial ecology, ecology, plant breeding and biochemistry, EPA proposed in 1994 to exempt plant-incorporated protectants that plants normally possess and are moved between closely related plants. EPA's preferred approach to describing for regulatory purposes this category of plant-incorporated protectants used the criterion of sexual compatibility, including hybridization achieved by wide and bridging crosses.

1. *1994 Proposal*. Plants that are sexually compatible form viable zygotes through the fusion of gametes in sexual hybridization. In the **Federal Register** of November 23, 1994 (59 FR 60519), EPA proposed that plant-pesticides (now plant-incorporated protectants) would be exempt from all FIFRA requirements, except for an adverse effects reporting requirement, if the genetic material that leads to the production of the pesticidal substance is derived from plants that are sexually compatible with the recipient plant and has never been derived from a source that is not sexually compatible with the recipient plant. EPA proposed in 1994 that this exemption for ''sexually compatible'' plant-incorporated protectants would apply regardless of how a plant-incorporated protectant came to be in the plant; e.g., whether they evolved naturally in the plant, or were introduced through traditional breeding or the techniques of genetic engineering, as long as the donor and recipient plant are sexually compatible. EPA's proposal to exempt plant-incorporated protectants from

sexually compatible plants subsumed plant-incorporated protectants in plants propagated vegetatively. In 1994, EPA also published companion proposals under section 408 of the FFDCA that would exempt all residues of plant-incorporated protectants derived from plants sexually compatible with the recipient plant (59 FR 60535, 60542). EPA caveated the 1994 proposals by noting that the Agency did not intend to exempt a plant-incorporated protectant that has been modified so that it is significantly different functionally from the plant-incorporated protectant as it occurs in the source organism (59 FR at 60524). In 1994, EPA also offered for comment two alternative proposed approaches based in whole or in part on taxonomy. All three of these approaches were based on the premise that closely related plants, whether described by sexual compatibility or taxonomy, were unlikely to present novel exposures.

In the 1994 proposals, sexually compatible, when referring to plants, was described as capable of forming a viable zygote through the fusion of two gametes including the use of bridging or wide crosses between plants. Basically this described the traditional breeding techniques of controlled pollination among plants expressing desired traits, seed collection and selection of the resulting progeny for enhanced combinations.

In the 1994 proposals, ''bridging crosses between plants'' were defined as the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote. In the 1994 proposal, ''wide crosses between plants'' would be to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre- and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures, or any other technique that the Administrator determines meets this definition.

The Agency also requested in the 1994 **Federal Register**, comment on an exemption criterion based on the process (e.g., rDNA) used to introduce the plant-incorporated protectant into a plant (50 FR at 60514 and 60530). In this approach, plant-incorporated protectants developed through techniques other than those of modern genetic engineering (e.g., rDNA) would be exempted, i.e., those developed through conventional plant breeding would be exempted. Categories of those plant-incorporated protectants that were not exempted could subsequently be considered for exemption on the basis of risk potential. The FIFRA Scientific Advisory Panel (SAP) and the Biotechnology Science Advisory Committee at a joint meeting on January 21, 1994, considered the utility of such an approach, and supported use of a criterion based on rDNA methodologies, based on: the success of the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (e.g., see 59 FR 34496, July 5, 1994); uncertainties about how a gene will function in the new genetic background; and to build public confidence in the products of genetic engineering. The joint meeting report also recommended that further exemptions . . .should be used in conjunction with the criterion based on methodology. The SAP specifically recommended that ''[f]or example, when rDNA methodologies are used to exchange genes between sexually compatible crop plants, the products would be exempt from additional regulation'' (Ref. 4 at 10).

2. *Public comments*. In response to its November 23, 1994 **Federal Register** request for comment on the proposal to exempt plant-incorporated protectants derived from plants sexually compatible with the recipient plant (59 FR at 60533), EPA received 52 comments addressing the issue of scope of exemption. These comments presented a broad range of views. Twenty-seven comments discussed the merits of EPA's 1994 preferred approach; i.e., the exemption proposal based on sexual compatibility between the donor and recipient plants. The majority of these comments favored such an approach, although some commenters favored EPA's alternative proposed approach based in part on taxonomy (Option 3). Others among the 27 comments expressed reservation about the rationale underlying the preferred and alternative approaches, i.e., relatedness among plants being equated to potential for novel exposures. For example, one comment stated that while superficially attractive, EPA's preferred approach was flawed in that it did not consider nontarget exposure by the introduction of a plant into an ecosystem in which it did not evolve.

EPA also received 35 comments on the propriety of relying on the process by which the genetic material is introduced into the plant as a criterion for defining the scope of EPA's regulatory oversight. Twenty of these comments supported an approach based on process, i.e., that those plant-incorporated protectants introduced by rDNA would be regulated, while conventional breeding would be exempt. These comments urged the Agency not to exempt plant-incorporated protectants introduced into the recipient plant by the processes of genetic engineering, regardless of whether they were derived from plants sexually compatible with the recipient plant. The comments focused on a common concern, which can be represented by the following excerpt:

> Genetic engineering (particularly recombinant DNA [rDNA] methodologies), represents a fundamental technical advance over traditional plant breeding in the ability to manipulate plants genetically. . . . given the fact that rDNA technologies represent such a fundamental technical advance over plant breeding, and given that plant-pesticides are by their very nature toxic substances, all plant-pesticides produced via rDNA methodologies should undergo some form of review under both FIFRA and FFDCA. . . (Ref. 5).

3. *Current status*. In companion documents published elsewhere today in this issue of the **Federal Register**, EPA exempts plant-incorporated protectants derived through conventional breeding from sexually compatible plants. In that document, EPA describes conventional breeding as the creation of progeny through either: The union of gametes, i.e., syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses; or vegetative reproduction. Conventional breeding does not include use of the techniques of genetic engineering. It does not include use of: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion.

In this supplemental document, EPA specifically requests comment on two proposed alternative regulatory approaches for plant-incorporated protectants derived through genetic engineering (e.g., rDNA) from plants sexually compatible with the recipient plant.

B. Description of Alternative Proposals

Under the first alternative, all plant-incorporated protectants derived from plants sexually compatible with the recipient plant would be exempt

regardless of the technique used to introduce the plant-incorporated protectant into the plant. Under the second alternative, EPA would establish a notification process that would implement a screening procedure to determine whether a plant-incorporated protectant derived through genetic engineering from a plant sexually compatible with the recipient plant qualified for exemption.

1. *Exemption of all plant-incorporated protectants derived from plants sexually compatible with recipient plant.* EPA will review comment on this supplemental proposal, and reevaluate risk in light of recent information and the comments. If EPA concludes that all plant-incorporated protectants derived from plants sexually compatible with the recipient plant meet the criteria for an exemption from all FIFRA requirements, except for the adverse effects reporting requirement at 40 CFR 174.71, and the requirements of a tolerance under section 408 of the FFDCA for the residues of such plant-incorporated protectants, the following language would be substituted in the regulatory text at 40 CFR part 174.

i. *FIFRA.* The following language would be substituted at 40 CFR 174.25:

§ 174.25 Plant-incorporated protectant from sexually compatible plant.

A plant-incorporated protectant is exempt if all of the following conditions are met:

(a) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is derived from a plant that is sexually compatible with the recipient plant.

(b) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance has never been derived from a source that is not sexually compatible with the recipient plant.

(c) The active ingredient has not been functionally modified from the source.

Sexually compatible, when referring to plants, would mean capable of forming a viable zygote through the union of two gametes, including the use of bridging crosses or wide crosses between plants. Sexually compatible would include the recombination that occurs in hybridization between sexually compatible plants, e.g., the formation of a viable zygote by the pollination of one corn plant with another. It would also include plant-incorporated protectants that normally occur in the plant, when such plants are propagated vegetatively, e.g., banana.

Functionally modified from the source, when referring to plant-incorporated protectants only, would mean the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance, has been modified in such a way that the pesticidal substance produced from the genetic material in the recipient plant is functionally different than the pesticidal substance produced in the source. In the 1994 proposal (59 FR at 60524), EPA explained that in proposing the exemptions the Agency did not intend to exempt plant-incorporated protectants that are significantly different in function from the plant-incorporated protectant as it occurs in the source. EPA believes this limitation would be appropriate because rearrangements or modifications of the genetic sequence encoding a pesticidal substance could, for example, result in a plant-incorporated protectant with significantly different functions from the function in the source plant. For example, if the pesticidal substance is an enzyme, it could be modified so that it acts on a different substrate in the recipient plant than it did in the source plant (Refs. 6 and 7). Such a significantly modified plant-incorporated protectant would not be eligible for the exemption because it would not present risks similar to the substance prior to modification, nor would the base of experience on which EPA relies for support of the exemption necessarily be relevant. If the genetic material encoding the pesticidal substance has been modified in such a way that the pesticidal substance functions differently in the recipient plant than it did in the source plant, the analysis performed to determine that the plant-incorporated protectant 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, would not apply. EPA does not intend that the concept of functionally modified from the source would apply to modifications, in the sequence of the genetic material portion of the plant-incorporated protectant, that may be needed to achieve correct expression, but which have no significant effect on the specificity or function of the pesticidal substance.

In order to clearly indicate in the regulatory text that significantly modified plant-incorporated protectants would not be covered by this exemption, EPA would include a statement that the exemption does not apply to a plant-incorporated protectant that has been functionally modified from the source, and a definition of functionally modified from the source at § 174.3 as follows:

Functionally modified from the source, when referring to plant-incorporated protectants only, means the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance has been modified in such a way that the pesticidal substance produced from the genetic material in the recipient plant is functionally different than the pesticidal substance produced in the source.

The definition of ''bridging crosses between plants'' would continue to read as follows:

Bridging crosses between plants means the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.

EPA is also considering whether to modify the definition of ''wide cross'' by including ''protoplast fusion.'' In part, this will depend on the comment received in response to this proposal (see Unit III.D.6.), and on whether EPA receives information demonstrating that novel exposures would be unlikely even with such an expanded definition.

''Genetic material that encodes for a pesticidal substance'' or leads to the production of a pesticidal substance does not include regulatory regions or noncoding, nonexpressed nucleiotide sequences.

ii. *FFDCA section 408.* To exempt all residues of the pesticidal substance portion of plant-incorporated protectants derived from plants sexually compatible with the recipient plant, regardless of the method by which the plant-incorporated protectant is introduced into the plant, EPA would substitute the following language at 40 CFR 174.479:

§ 174.479 Pesticidal substance from sexually compatible plant; exemption from the requirement of a tolerance.

Residues of a pesticidal substance that is part of a plant-incorporated protectant derived from a sexually compatible plant are exempt from the requirement of a tolerance if all the following conditions are met:

(a) The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is derived from a plant that is sexually compatible with the recipient food plant.

(b) The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance has never been derived from a source that is not sexually compatible with the recipient plant.

(c) The active ingredient has not been functionally modified from the source.

(d) The residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health.

2. *Case-by-case review of eligibility for exemption through notification process.* EPA also requests comment on a notification process that would implement a screening procedure for plant-incorporated protectants derived through genetic engineering from plants sexually compatible with the recipient plant.

Under this alternative to registration, as part of the final rule EPA would establish criteria to determine whether a plant-incorporated protectant derived through genetic engineering from plants sexually compatible with the recipient plant is ''substantially equivalent'' to a plant-incorporated protectant that could have been derived through conventional breeding from plants sexually compatible with the recipient plant. Anyone intending to sell or distribute a plant-incorporated protectant could submit a notification to EPA seeking a determination that a plant-incorporated protectant qualified for this exemption, accompanied by an analysis demonstrating that the plant-incorporated protectant derived through genetic engineering from plants sexually compatible with the recipient plant is substantially equivalent to a plant-incorporated protectant derived through conventional breeding from sexually compatible plants. The Agency would review the submission and evaluate it against the regulatory criteria to determine whether the plant-incorporated protectant met the criteria for an exemption. At the end of this process, the submitter would receive a letter describing EPA's conclusion. If EPA determines that the plant-incorporated protectant met the criteria, it would be exempt from further regulation under FIFRA, except for the adverse effects reporting requirement at 40 CFR 174.71. However, if EPA determines that the plant-incorporated protectant is not substantially equivalent to a plant-incorporated protectant derived through conventional breeding from sexually compatible plants, a registration would be required prior to its sale or distribution, as well as, if residues of the plant-incorporated protectant are in or on food or feed, a tolerance exemption.

This proposed alternative would be an intermediate measure between exemption of the plant-incorporated protectant and registration, and would ensure that those plant-incorporated protectants derived through genetic engineering from plants sexually compatible with the recipient plant are as safe as those derived through conventional breeding. It would allow the Agency to conduct a case-by-case review of these products to address those endpoints with which the commenters expressed the greatest concern over the strength of the Agency's factual basis for exempting the group as a whole. This notification procedure would, however, impose a lower degree of oversight than the standard requirements of pesticide registration. For example, such ''substantially equivalent'' plant-incorporated protectants would only be subject to the adverse effects reporting requirements at 40 CFR 174.71; unlike registered pesticides, manufacturers would not be required to obtain establishment numbers or submit section 7 production reports. Moreover, the plant-incorporated protectants would not be required to bear FIFRA labels. Nor would the Agency envision requiring the submission of the standard battery of toxicity testing currently required under 40 CFR part 158; rather, only data relevant to a determination of substantial equivalence would be required to be submitted.

Any person who sells or distributes in commerce a plant-incorporated protectant derived through genetic engineering without having obtained either a determination of equivalence or a registration would violate FIFRA section 12(a)(1)(A). Products sold or distributed in commerce in violation of section 12 are subject to seizure, pursuant to FIFRA section 13. In addition, any person selling or distributing such products are subject to the penalties provided in FIFRA section 14.

This option would only exempt a plant-incorporated protectant from the registration requirements under FIFRA. If the plant-incorporated protectant was intended to be used in a food plant, resulting in pesticide chemical residues, a tolerance exemption would need to be established, prior to the introduction of the food in commerce. Without a tolerance exemption, any food bearing residues of the plant-incorporated protectant would be adulterated, pursuant to section 402(a)(2)(B) of FFDCA, and subject to seizure by FDA. An application for an exemption from the tolerance requirement could be submitted concomitantly with the submission for exemption from FIFRA registration requirements.

i. *Criteria for determining substantial equivalence.* Currently, EPA believes that the following considerations could be developed into criteria relevant to determining whether a plant-incorporated protectant is substantially equivalent to a plant-incorporated protectant that could have been derived through conventional breeding from sexually compatible plants.

a. The source of the gene of interest is a plant sexually compatible with the recipient plant, and the active ingredient has not been functionally modified from the source.

b. Any pesticidal substance is not present at deleterious or injurious levels.

c. The plant-incorporated protectant has the same tissue expression pattern, including levels of expression, observed in varieties of the recipient plant currently in widespread agricultural use or consumed by the U.S. population.

d. Any inert ingredient is on the list of approved inert ingredients at subpart X of 40 CFR part 174.

Prior to adopting criteria in any final rule, EPA would seek the advice of its SAP on criteria appropriate for evaluating whether a plant-incorporated protectant derived through genetic engineering from plants sexually compatible with the recipient plant is substantially equivalent to a plant-incorporated protectant that could have been derived through conventional breeding from sexually compatible plants.

ii. *Where to submit notification.* By mail, written notifications would be submitted to: Document Processing Desk (7504C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person, deliver requests to: Environmental Protection Agency, Crystal Mall #2, Room 258, Document Processing Desk, 1921 Jefferson Davis Hwy., Arlington, VA. In order to expedite processing, the request must be marked ''Attention: Plant-Incorporated Protectant Notification Review.''

iii. *Contents of notification.* The notification could include, for example:

a. Name and address of requester and name, address, e-mail address, and telephone number of a person who may be contacted for further information.

b. Data or information relating to a determination that the specific plant-incorporated protectant and any inert ingredient(s) are substantially equivalent to a plant-incorporated protectant derived through conventional breeding from sexually compatible plants. Such information could include:

- A detailed description of the introduced genetic material, including certification that the organism(s) that is the source of the genetic material encoding the pesticidal substance is a plant that is sexually compatible with the recipient plant.
- The source of any selectable markers.
- The product(s) of the genetic material, and whether and how the

products (both active and inert ingredients) are expected to affect the behavior of the recipient plant.

• Information on all regulatory sequences including those affecting specificity of tissue expression and information on the level of expression of the structural genes.

• Stability of the introduced genetic material.

c. Any other information the requester might consider relevant.

iv. *CBI*. To assert a claim of confidentiality, the requester would have to comply with the applicable procedures in 40 CFR 174.9. Section 174.9(a) states that failure to assert a claim of confidentiality at the time the information is submitted to EPA will be considered a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.

v. *EPA review*. EPA would review and evaluate notifications as expeditiously as possible. If the request received by EPA is complete (e.g., no additional information is required by EPA or submitted by the requester as supplemental information, or no amendment to the request made), EPA would complete its evaluation in between 150 and 180 days of receipt of the request. EPA may require additional information from the submitter in order to assess the equivalence of the plant-incorporated protectant derived through genetic engineering to a plant-incorporated protectant derived through conventional breeding from sexually compatible plants. Should EPA require additional information or the requestor submit supplemental information, more than 150 to 180 days may be required to complete the assessment. At the conclusion of the review, EPA will supply a letter to the submitter describing the Agency's evaluation and determination.

The submitter may supplement, amend, or withdraw his or her notification in writing, without EPA approval, at any time prior to EPA's determination. The withdrawal of a request shall be without prejudice to the resubmission of the notification at a later date.

C. Request for Comment on Proposed Alternative Regulatory Approaches

EPA requests comment on the following issues for the proposed alternatives described in Unit III.B. EPA requests that respondents comment on the proposed alternative proposals, and include consideration of the issues described in Unit III.D. in their comments on Unit III.C.

1. *Distinction between proposed approaches*. The two proposed regulatory alternatives distinguish between plant-incorporated protectants on the basis of the process by which the plant-incorporated protectant has been introduced into the plant. EPA requests comment on whether a distinction based on the process of genetic modification is justified in light of the state of the science, including the specific questions and risk concerns raised by the comments received in response to the Agency's 1994 proposal, and briefly described in Unit III.D.

Given the issues described in Unit III.D. with respect to plant-incorporated protectants derived through genetic engineering from plants sexually compatible with the recipient plant, are such products sufficiently analogous to plant-incorporated protectants derived from conventional breeding that the Agency can rely on the factual basis, described in companion documents published elsewhere in this issue of the **Federal Register** for plant-incorporated protectants derived through conventional breeding, to support the exemption in the proposed regulatory alternative described in Unit III.B.1.

2. *Notification process*. EPA requests comment on the utility of a notification process for determining whether a plant-incorporated protectant derived through genetic engineering from plants sexually compatible with the recipient plant is equivalent to a plant-incorporated protectant derived through conventional breeding from sexually compatible plants. EPA is particularly interested in comments addressing whether this level of regulatory oversight is necessary to address the potential risks from plant-incorporated protectants derived through genetic engineering from plants sexually compatible with the recipient plant, and whether this level of oversight would adequately address the safety questions surrounding these products. Can the factual basis, described in companion documents published elsewhere in this issue of the **Federal Register** for plant-incorporated protectants derived through conventional breeding, be used on a case-by-case basis to support exemption in the proposed regulatory alternative described in Unit III.B.2.

EPA requests comment on the criteria described in Unit III.B.2.i. for evaluating ''substantial equivalence.'' For example, EPA requests comment on whether reliance on plants currently in widespread agricultural use, or consumed by the U.S. population is an appropriate standard, or whether it would be more appropriate to compare the resulting plant-incorporated protectant to its parental organisms. The Agency would welcome any information or data that might be of assistance in developing proposed criteria for use in its potential notification process. EPA would particularly welcome comment on whether the criteria described in Unit III.B.2.i., would capture all of the potential pleiotropic effects of concern with respect to this subgroup of plant-incorporated protectants. In light of the fact that FDA is proposing to review all genetically engineered foods for possible effects resulting from the point of insertion, EPA requests comment on whether there is any need for EPA to also examine this endpoint. The Agency is concerned that the final criteria not prevent it from examining all possible parameters of interest, but also recognizes the need for determinate criteria for this option to function effectively.

EPA requests comment on whether the potential information needs described in Unit III.B.2.iii. are adequate for demonstrating substantial equivalence with plant-incorporated protectants derived through conventional breeding from sexually compatible plants. EPA solicits comment on whether there are any additional types of information that might be useful for demonstrating substantial equivalence.

3. *Variant of notification process for broader group of plant-incorporated protectants*. Some components in plants are widely distributed across the plant kingdom and thus may be found in many plant populations, some of which are not sexually compatible with each other. EPA requests comment on whether a notification process similar to one described in Unit III.B.2. could be developed for plant-incorporated protectants from outside the gene pool of the recipient plant, but nonetheless equivalent to those that evolved within the gene pool of the recipient plant.

EPA notes that to develop a notification process for such plant-incorporated protectants, EPA must first develop criteria to describe such plant-incorporated protectants. EPA would seek the advice of its SAP in developing proposed criteria. Some of the factors EPA might ask the SAP to consider in developing criteria for proteinaceous substances include amino acid sequence homology, post-translational processing, structure, stability, receptor/ligand specificity, substrate specificity and equivalence of reaction products. For non-proteinaceous plant-incorporated protectants, the chemical composition

and structure of the introduced plant-incorporated protectant could be compared with the plant-incorporated protectants that are normally components of the recipient plant. This information on composition and structure could then be related to the function of the introduced plant-incorporated protectant. Other factors that might also be considered in this determination include:

i. When during the plant's life cycle the pesticidal substance is produced.

ii. In which part of the plant (e.g., leaves, roots, fruit) the pesticidal substance is produced.

iii. The levels at which it is produced. EPA would welcome any information or data that might be of assistance in developing proposed criteria for use in this variant of a potential notification process.

D. Request for Comment on Risk Issues

Several risk issues have been raised for plant-incorporated protectants derived through genetic engineering from plants sexually compatible with the recipient plant. EPA requests comment on these issues, described in this unit, in the context of the two proposed alternative regulatory approaches described in Unit III.B.

1. *Levels of toxicants*? Some comments described toxic substances naturally occurring in plants in sexually compatible populations, and expressed concern that EPA's 1994 proposal to exempt all plant-incorporated protectants derived from sexually compatible plants did not include consideration of the potential for risk associated with increases in levels of such substances. These comments implied that such increases are more likely to occur with plant-incorporated protectants derived through genetic engineering from sexually compatible plants. One commenter stated, for example, that use of ''artificial regulators (regardless of source) may allow genes to escape natural dampening mechanisms and to be produced at extremely high levels not found in naturally occurring or traditionally bred plants. Artificial promotors may also result in toxins being produced in tissues where they are not ordinarily produced, or in some cases in every cell of the plant'' (Ref. 8). Another commenter stated that ''EPA appears to be ignoring a basic axiom of toxicology, e.g., the dose makes the poison'' (Ref. 5).

In a companion document published elsewhere in this issue of the **Federal Register**, EPA, recognizing that increases in levels of toxicants can occur in conventional breeding as well as in varieties developed through genetic engineering, imposed a condition on the exemption at 40 CFR 174.479 to address this concern. In order to allow EPA and FDA to act expeditiously, should a rare instance of levels high enough to render food injurious or deleterious occur, residues of the pesticidal substances derived through conventional breeding from sexually compatible plants qualify for exemption from the tolerance requirement only if the ''residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health.''

EPA requests comment on whether, in the context of food and FFDCA section 408 requirements, such a limitation is sufficient to address the same concern for residues of pesticidal substances derived through genetic engineering from plants sexually compatible with the recipient plant, should EPA exempt this later subgroup, as described in Unit III.B.1.

EPA also requests comment on whether, in the context of FIFRA requirements, this condition would be sufficient to address the concerns that have been raised with respect to potential effects on nontarget organisms for plant-incorporated protectants derived through genetic engineering from plants sexually compatible with the recipient plant.

EPA requests comment on whether such a limitation is meaningful for those plant-incorporated protectants not in plants used for food or feed (e.g., trees), given that deleterious or injurious substances in such semi-managed plants naturally tend to greater ranges of expression than seen in crop plants, including higher ranges of expression (Ref. 9).

Commenters also discussed the potential for changes in promotors or other regulatory elements to affect tissue specific expression of toxicants, i.e., where previously a toxicant was expressed only in trace amounts in the edible part of the plant, a new promotor might result in high levels of expression in the edible part. EPA requests comment on whether such events are more likely to occur with plants-incorporated protectants derived through genetic engineering than with those derived through conventional breeding from sexually compatible plants. EPA also requests comment on whether the condition placed on the tolerance exemption at 40 CFR 174.479, that the ''residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health'' are adequate to address this concern for plant-incorporated protectants derived through genetic engineering from plants sexually compatible with the recipient plant in the context of FFDCA section 408. Is this condition sufficient to address the concern for FIFRA?

2. *Potential for production of a novel toxicant*? In developing the final rule published elsewhere in this issue of the **Federal Register** in companion documents, EPA also considered the possibility that expression of a transgenic protein could result in the plant producing a toxicant not observed in either of the parent species. An example of this would be the case of somatic hybrids between *Solanum brevidans* and *S. tuberosum* producing the toxicant, demissine, not found in either parental line. *Laurila et al.* (Ref. 10) advanced the hypothesis that the hydrogenase enzyme of *S. brevidans* produced the toxicant by hydrogenating solanine, a compound that is found in *S. tuberosum* but not in *S. brevidans*. Portions of the metabolic pathways necessary to produce this substance apparently existed in the parental species, and the mingling of the genetic material resulted in a complete pathway for production of demissine. This example suggests that novel metabolic pathways could be created in a plant through the introduction of a single gene, should other components of the pathway already be present in the plant. EPA requests comment on whether there is any difference in the probability of this occurring in plants in sexually compatible populations into which the plant-incorporated protectant was introduced by genetic engineering as compared to conventional breeding.

3. *Consequences of transfer of ability to produce higher levels of a plant-incorporated protectant to wild or weedy relatives?* EPA also received comments on the potential for a food crop or other commercial plant engineered to produce unusually high levels of a plant-incorporated protectants to ''interbreed with a wild, weedy relative which in turn would become very resistant to certain insect pests. The wild relative, now free from certain pest damage, could increase in number and either become a much worse pest itself or disrupt an ecosystem. . .'' (Ref. 5). Gene flow from crop plants to wild relatives has been observed in plants developed through conventional breeding in sexually compatible populations (Refs. 11 and 12). It has not yet been established whether gene flow into feral populations, from either genetic engineered or conventionally bred plants, can endow wild relative

populations with a selective advantage that might enhance their potential for weediness.

Given that wild relatives of crop plants are likely to already possess traits similar to those in related crop plants, and express these traits at a higher range of levels than crop plants, what is the probability that outcrossing of the ability to express such traits at high levels from crop plants to wild or weedy relatives, would give the wild relatives a competitive advantage?

EPA also requests comment on whether this phenomenon could result in significantly different consequences when comparing gene flow between plant-incorporated protectants derived through genetic engineering from sexually compatible plants as compared to plant-incorporated protectants derived through conventional breeding from sexually compatible plants.

4. *Does use of antibiotic or herbicide resistance or other selectable markers present risk?* Because genetic engineering techniques are so precise, a gene can be excised from the source organism without unwanted, extraneous genetic material. The precise gene can then be introduced into the recipient organism. However, there can be other genetic information on the construct used to introduce the desired gene, and although this genetic information may also be precise, it may not be part of the gene pool of the recipient plant, e.g., genes for herbicide resistance used as a selectable marker. In a companion document published elsewhere in this issue of the **Federal Register**, EPA describes its determination that the Agency will adopt the definition of inert ingredient it proposed in 1994. An inert ingredient for plant-incorporated protectants is ''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.'' In that same companion document, EPA also describes the qualification that a plant-incorporated protectant can only be exempt if the inert ingredient(s) used with an exempt active ingredient is on the list of approved inert ingredients at subpart X of 40 CFR part 174.

EPA anticipates that a plant-incorporated protectant qualifying for exemption under the proposed regulatory alternative described in Unit III.B.1. would be composed of an active ingredient derived through genetic engineering from a plant sexually compatible with the recipient plant and an ingredient on the approved list at subpart X of 40 CFR part 174. In light of this assumption, and given that the inserted structural gene of interest (for EPA's purposes, the gene encoding the pesticidal substance) is taken from the same gene pool in which it normally exists, EPA requests comment on whether, even if the structural gene of interest in the inert ingredient is derived from a source not sexually compatible with the recipient plant, the plant-incorporated protectant can still be considered to be ''substantially equivalent'' to a plant-incorporated protectant that could have been derived through conventional breeding. Specifically, EPA requests comment on whether the risks associated with such plant-incorporated protectants derived through genetic engineering are any greater that the risks associated with plant-incorporated protectants derived through conventional breeding.

5. *Should protoplast fusion be included in the definition of wide cross?* EPA requests comment on whether protoplast fusion should be added to the definition of wide crosses. In the official comment period for the November 23, 1994 **Federal Register**, EPA received one comment that suggested protoplast fusion should be included among the techniques listed in the definition of wide crosses between plants. A protoplast is made in the laboratory through the removal of the cell walls of somatic cells. A somatic cell is a type of cell that forms plant vegetative tissues and organs and is distinguished from a germ cell which undergoes meiosis to produce reproductive tissues (e.g., pollen and egg cells). In the technique of protoplast fusion, protoplasts from two different plants are fused together, producing a hybrid somatic cell with a genetic makeup resulting from the combination and sorting of the two plant genomes. The hybrid somatic cell is grown on specialized media into a mature plant. In support of the request, the commenter argued that the hybridization of somatic cells (i.e., protoplast fusion) has a history of use to artificially induce sexual compatibility. For the most part, the more closely related the plants donating the protoplasts used for the fusion, the more likely a viable hybrid will be obtained. Currently, in a companion document published elsewhere in this issue of the **Federal Register**, EPA specifically excludes cell fusion from the definition of conventional breeding, with cell fusion defined as ''the fusion *in vitro* of two or more cells or protoplasts.''

EPA requests comment on whether protoplast (or cell) fusion, or alternatively, some subgroup of fusions (e.g., intraspecific or intrageneric), should be included in the definition of wide crosses in light of the following dietary and environmental considerations. First, in the example provided in Unit III.D.2. describing the potential for creation of new toxicants, dimissine arose through the fusion of protoplasts of *S. tuberosum* and *S. brevidans*. Second, the FDA in its 1992 ''Statement of Policy: Foods Derived from New Plant Varieties'' (57 FR 22984, May 29, 1992) expresses a concern that protoplast fusion might confer on food from the host plant the allergenic properties of food from the donor plant.

IV. Notice of Data Availability and Request for Comment

In April 2000, the NAS released a report entitled ''Genetically Modified Pest-Protected Plants: Science and Regulation'' (Ref. 13). Prepared by an expert committee, this report examined the proposals offered by EPA in the November 23, 1994, **Federal Register** (59 FR 60496). This report recommended that EPA reconsider the Agency's proposed exemptions, raising a number of questions, primarily with respect the Agency's factual support for the exemptions. EPA requests comment on the information, analyses, and conclusions contained in the NAS report only with respect to those portions of its original proposals that remain pending. EPA is not soliciting comments on any issues beyond those raised specifically by the information contained in the NAS report; for example, the NAS report raised no issues with respect to the Agency's analyses of the human health risks associated with viral coat proteins. Any comments submitted on such issues will be treated as having been submitted after the close of the comment period, as the Agency has twice solicited comment on these issues, in 1994 and 1997.

The NAS report presents a number of competing considerations without necessarily providing the Agency with a ready basis for resolving these issues. For example, the report (Ref. 13 at 44-46) states:

> The 1987 NAS report noted that the risks associated with rDNA-engineered organisms are ''the same in kind'' as those associated with unmodified organisms and organisms modified by other methods. The committee agrees with that statement for pest-protected plants in that both transgenic and conventional plants may pose certain risks and the resulting plant phenotypes are often similar. Transgenic breeding techniques can be used to obtain the same resistance

phenotype as conventional methods (for example resistance to microbial pathogens, nematodes, and insects). Because both methods have the potential to produce organisms of high or low risk, the committee agrees that the properties of a genetically modified organism should be the focus of risk assessments, not the process by which it was produced (point 3).

In this regard, the committee found that:

There is no strict dichotomy between or new categories of the health and environmental risks that might be posed by transgenic and conventional pest-protected plants.

The committee recognizes that the magnitude of the risk varies on a product by product basis. The committee also agrees with points 1 and 2 in the sense that the potential hazards and risks associated with the organisms produced by conventional and transgenic methods fall into the same general categories. As this report discusses, toxicity, allergenicity, effects of gene flow, development of resistant pests, and effects on non-target species are concerns for both conventional and transgenic pest-protected plants.

The committee agrees with the 1987 NAS principles in that the magnitude of quantitative risk does not depend on the genetic-modification process. It depends on the new genes that are expressed in the plant. End points of risk (such as illness in humans and declines in nontarget species) can be the same regardless of whether a specific new gene was transferred by conventional or transgenic methods. For example, if the same alkaloid gene is transferred by sexual hybridization or *Agrobacterium*-mediated insertion, the risk should be similar. If a gene coding for a novel trait is transferred by transgenic methods, but cannot be transferred by conventional methods, it is the expressed trait that requires scrutiny, not the method of transfer.

Yet by contrast, on page 128, the report states:

The committee recognizes the realistic limitations of overseeing the pesticidal substances in conventional pest-protected plants and, given their history of safe use, recognizes that there are practical reasons for exempting those substances. However, the committee questions the scientific basis used by EPA for this exemption because no strict dichotomy or new categories appear to exist between the risks to health and the environment that might be posed by conventional and transgenic pest-protected plant products (section 2.2.1).

The categorical exemption also applies to transgenic pest-protected plant products that contain transgenes from sexually compatible species, and the committee questions the scientific basis for this exemption as well, specifically because the genes and gene products can be expressed at concentrations far greater than the concentrations at which they are naturally expressed (sections 2.4.1 and 2.5.2). Even though the risks of many transgenic pest-protected plants containing genes from sexually compatible species are expected to be low and would justify exemption, lack of experience with these products and public concern over genetic engineering suggest that a blanket exemption for them is inadvisable.

EPA requests comment on how to best reconcile these competing considerations.

V. Proposed Alternative Regulatory Approaches to Plant-Incorporated Protectants Based on Viral Coat Proteins

This Unit solicits additional comment on the two alternative regulatory approaches the Agency discussed in greater detail in the 1994 proposal (59 FR 60496, e.g., see 60525 through 60528). EPA solicits additional public comment on these alternatives in light of the issues raised by the NAS report, as well as on the issues raised by commenters on the 1994 proposal. The Agency intends to consider public comments and make final determinations to complete these other rulemakings within 9 to 12 months after the close of the comment period for the supplemental proposal, which is currently set at 30 days. Until the Agency takes a final action on these other exemptions, the Agency intends to maintain its current practices on regulation of plant-incorporated protectants.

A. History

Coat proteins are those substances that viruses produce to encapsulate and protect the nucleic acids comprising their genetic material. When the genetic material encoding the information for making the coat protein of a plant virus is introduced into a plant's genome, the plant becomes resistant to infection by the virus donating the genetic material for the coat protein (and frequently to viruses closely related to the donor virus) (Refs. 14 and 15). This resistance is termed viral coat protein mediated-resistance or vcp-mediated resistance (Refs. 14 and 15). Coat proteins from plant viruses intended to be produced and used in living plants for vcp-mediated resistance to viral disease, along with the genetic material necessary to produce the coat proteins, are plant-incorporated protectants.

1. *1994 Proposal*. In the 1994 proposal, EPA proposed to exempt from all FIFRA requirements, except for the adverse effects reporting requirement at § 174.71, all plant-incorporated protectants based on coat proteins from plant viruses (Option 1) (59 FR at 60525). EPA also described an alternative option (Option 2) offering a more limited exemption (59 FR 60526). Under this alternative option, the exemption would be limited to those plant-incorporated protectants based on coat proteins from plant viruses that would have the least potential to confer selective advantage on free-living wild plant relatives of the plants containing these plant-incorporated protectants. Under Option 2, a coat protein would be exempt if:

The pesticidal substance is a coat protein from a plant virus and the genetic material necessary to produce the coat protein has been 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.

2. *Public comments*. In response to its November 23, 1994 **Federal Register** request for comment on the proposal to exempt plant-incorporated protectants based on the coat proteins of plant viruses, EPA received 65 comments. Many of the comments supported Option 1. Some of the comments supported adoption of Option 2. In the opinion of these commenters, Option 2 appropriately addresses concerns about the potential effects of outcrossing of plant-incorporated protectants based on coat proteins from plant viruses from crop plants to wild or weedy relatives. These comments pointed out that there is scientific evidence indicating that crops may transfer traits to wild relatives, and that many crops grown in the United States have wild relatives that are either native or have been introduced. These comments questioned the adequacy of available data to evaluate the probability that outcrossing of plant-incorporated protectants based on coat proteins from plant viruses could confer a selective advantage on wild or weedy relatives of crop plants. Approximately one-third of the comments opposed the exemption of plant-incorporated protectants based on coat proteins from plant viruses. Most of these comments offered no explanation for their opposition. Those who explained their opposition cited among their concerns, a potential for creation of more aggressive weeds and disturbance to centers of diversity

3. *Current status*. The Agency received scientific information both from commenters supporting Option 1 and commenters supporting Option 2. In this supplemental document, EPA requests additional public comment on the proposed alternative approaches discussed in the 1994 **Federal Register** and the risk considerations associated with weediness raised in comment. EPA will consider all comments received on this proposal, including comments received in response to the original proposal in 1994, and any comments received in response to this supplemental document, in arriving at a decision on how to proceed.

B. Description of Proposed Modification to Language of Proposed Exemption

Were EPA to implement either of the two options proposed in 1994, it would modify the language to clearly state that plant-incorporated protectants that are significantly different in structure or function from the plant-incorporated protectant as it occurs in the source would not be exempt.

In the 1994 proposal (59 FR at 60524), EPA explained that the Agency did not intend to exempt plant-incorporated protectants that are significantly different in structure or function from the plant-incorporated protectant as it occurs in the source. EPA believes this limitation is appropriate for coat proteins from plant viruses because rearrangements or modifications of the genetic sequence encoding a pesticidal substance could, for example, result in a plant-incorporated protectant with significantly different functions from the function in the source plant. For example, if the pesticidal substance is an enzyme, it could be modified so that it acts on a different substrate in the recipient plant than it did in the source plant (Refs. 6 and 7). Such a significantly modified plant-incorporated protectant would not be eligible for the exemption. It would not necessarily present risks similar to the substance prior to modification, nor would the base of experience on which EPA relies for support of the exemption necessarily be relevant.

Should EPA implement either Option 1 or Option 2, the Agency would include a statement that the exemption does not apply to a plant-incorporated protectant functionally modified from the source.

C. Request for Comment

The NAS report recommends that the:

> 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. 13 at 132)

The NAS bases its recommendation primarily on a lack of information on the effects of the transfer of genes conferring pest resistance from crop plants to weedy or wild relatives.

EPA solicits any additional information that might assist the Agency in determining whether it should implement Option 1, i.e., exempt all plant-incorporated protectants based on viral coat proteins, or Option 2, i.e., an approach that allows the Agency to evaluate the gene transfer risks associated with the introduction of viral coat proteins to each candidate plant. In addition, in light of the fact that USDA reviews potential plant-pest related issues relative to viral coat proteins, EPA requests comment on whether there is any need for EPA to also examine this endpoint.

EPA solicits comment on whether outcrossing of plant-incorporated protectants based on coat proteins from plant viruses could confer a selective advantage on wild or weedy relatives of crop plants, and if so, which crop plants. EPA would be particularly interested in receiving data on this issue.

EPA specifically requests comment on whether acquired virus-resistance could, for example: (1) Allow a wild plant to increase its range or population density; and/or (2) permit a plant's population density to increase so that the plant dominates a community where it was far less common before acquisition of the trait.

As a condition of the exemption, EPA could require applicants for the exemption to submit studies or generate data on the gene transfer risks associated with the candidate plant-incorporated protectant. Alternatively, EPA could require some degree of monitoring beyond that which would be required by the adverse effects reporting requirement. EPA requests comment on whether either of these approaches is necessary to address the concerns raised by the NAS and the commenters, or whether sufficient data currently exists to evaluate the gene transfer risks presented by the class of products that would be covered under either Option 1 or 2.

VI. Proposal on Plant-Incorporated Protectants that Act Primarily by Affecting the Plant

In this Unit, EPA solicits additional public comment on this proposed exemption and on the scientific issues raised by the NAS report (Ref. 13) and in comments received on the 1994 proposal. The Agency intends to consider public comments and make final determinations to complete these other rulemakings within 9 to 12 months after the close of the comment period for the supplemental proposal, which is currently set at 30 days. Until the Agency takes a final action on these other exemptions, the Agency intends to maintain its current practices on regulation of plant-incorporated protectants.

A. History

In the 1994 proposal (59 FR at 60525), EPA stated that one of the Agency's primary goals in regulating pesticides is to control the potential for adverse effects of pesticides on nontarget organisms. EPA reasoned that an important component in the evaluation of this potential is the way in which the pesticidal substance acts on the target pest since it would also likely affect nontarget organisms through the same mechanism. EPA further reasoned that some plant-incorporated protectants could act through mechanisms that are less likely to be directly toxic. The Agency stated a belief that although it is possible for these substances to adversely affect nontarget organisms, in most cases, they would pose significantly lower levels of environmental risk than plant-incorporated protectants with a generalized toxic mechanism of action. EPA identified those plant-incorporated protectants it thought would act in this manner as those that act primarily by affecting the plant so that the pest is inhibited from attaching to the plant, penetrating the plant's surface, or invading the plant's tissue.

1. *1994 Proposal*. In the November 23, 1994 **Federal Register**, EPA proposed to exempt from all FIFRA requirements, except for the adverse effects reporting requirement at 40 CFR 174.71, plant-incorporated protectants that act primarily by affecting the plant. The proposed regulatory text presented criteria to define mechanisms of action that exert the pesticidal action primarily by affecting the plant. The proposed language reads as follows:

> The pesticidal substance acts primarily by affecting the plant so that the target pest is inhibited from attaching to the plant, penetrating the plant, or invading the plant's tissue in at least one of the following ways:
>
> (i) The pesticidal substance acts as a barrier to attachment of the pest to the host plant, a structural barrier to penetration of the pest into the host plant, or a structural barrier to spread of the pest in the host plant, for example, through the production of wax or lignin, or length of trichomes (plant hairs).

(ii) The pesticidal substance acts in the host plant to inactivate or resist toxins or other disease-causing substances produced by the target pest.

(iii) The pesticidal substance acts by creating a deficiency of a plant nutrient or chemical component essential for pest growth on/in the host plant.

In the 1994 **Federal Register** document, EPA also indicated that it was considering extending this exemption to include substances such as plant hormones, because plant hormones act within the plant to ''primarily affect the plant'' and do not act directly on a target pest (59 FR at 60525, 60531). EPA requested public comment on whether plant hormones should be included in the exemption for plant-incorporated protectants that act primarily by affecting the plant.

2. *Public comments*. EPA received 23 comments that addressed this proposed exemption. A majority of comments supported the exemption of plant-incorporated protectants that act primarily by affecting the plant. The comments opposing the exemption primarily expressed concern about the potential for outcrossing of the trait from crop plants to wild relatives to increase weediness in the wild relatives. These concerns were variously described as concerns that outcrossing of these plant-incorporated protectants to wild relatives might result in the following outcomes: First, produce hardier plants that become weeds in agro-ecosystems; second, produce hardier plants that displace less hardy types; or, third, adversely impact nontarget organisms that depend for their survival on interactions with wild plants. Some comments urged EPA, in order to address the concerns, to adopt an approach that would subject a plant-incorporated protectant to regulation based on whether the plant-incorporated protectant was introduced into the recipient plant through use of rDNA or other techniques of modern biotechnology.

Fourteen comments responded to EPA's request for comment on whether to exempt plant hormones because they act primarily by affecting the plant. Most comments favored the exemption of plant hormones, stating that plant hormones act within the plant to affect the plant's behavior and do not have a toxic mode of action. A few comments favored exemption of plant hormones except when there is clear indication of unreasonable adverse effects to the plants as can occur in some plant diseases mediated by microorganisms. The comments disagreeing with the exemption expressed concern that outcrossing of plant hormones from crop plants to wild relatives might confer competitive advantage on the wild relatives.

3. *Current status*. In this supplemental document, EPA requests additional public comment on this proposed exemption and several risk issues raised in comment. EPA will consider all comments received on this proposal in arriving at a determination, including comments received in response to the original proposal in 1994, and any comments in response to this supplemental document.

B. Proposed Modification to Language of Proposed Exemption

The Agency is considering whether to modify the language of the proposed exemption as follows:

1. *Hypersensitive response*. Some comments suggested the hypersensitive response in plants would fall within the definition of a plant-incorporated protectant that functions by primarily affecting the plant. EPA understands the hypersensitive response to involve compounds that initiate, potentiate, or enhance hypersensitive or hypersensitive-type responses that result in area-specific necrosis in response to microbial invasion of plant tissue, thus limiting spread of the pathogen within the plant. EPA believes that the criteria of this exemption as proposed in 1994 would include substances involved in the hypersensitive response. EPA requests comment on whether, for regulatory clarity, the Agency should add language to the regulatory text at 40 CFR part 174 to clearly show that substances involved in hypersensitive or hypersensitive-type responses are exempt. That language would read as follows:

(iv) By initiating, potentiating, or enhancing hypersensitive or hypersensitive-type responses that, in response to invasion by a phytopathogen, results in necrosis of specific areas of plant tissue thereby limiting the spread of the pathogen in or on the plant.

2. *Functionally modified from the source*. As described in Unit V.B., in proposing the exemptions the Agency did not intend to exempt plant-incorporated protectants that are significantly different in structure or function from the plant-incorporated protectant as it occurs in the source (59 FR at 60524). The discussion at Unit III.B.i. and Unit V.B., applies equally to this proposed exemption for plant-incorporated protectants that act primarily by affecting the plant. In order to clearly indicate in the regulatory text that significantly modified plant-incorporated protectants would not be covered by this exemption, EPA would include a statement in this exemption that it does not apply to a plant-incorporated protectant that has been functionally modified from the source.

To this end, the following language would be added to the proposed exemption:

A plant-incorporated protectant acts primarily by affecting the plant if the plant-incorporated protectant has not been functionally modified from the source and the pesticidal substance:

(1) . . . .

The proposed definition of ''functionally modified from the source'' as described at Unit III.B.i., would also apply to this proposed language.

3. *Plant hormones*. Plant hormones are substances produced by plants that play a major role in the regulation of plant growth by either accelerating or retarding, through physiological action, the rate of growth or rate of maturation of the plant, or the produce thereof (Ref. 16). Known classes of plant hormones occurring naturally in plants are auxins, cytokinins, ethylene, abscisic acid, and gibberellins. Plant hormones are active in the living plant in very small quantities.

Were EPA to add specific language to this proposed exemption indicating that plant hormones act primarily by affecting the plant, the Agency would also add a definition of plant hormone in the context of plant-incorporated protectants at § 174.3 as follows:

Plant hormone, when referring to plant-incorporated protectants only, would mean naturally occurring auxins, cytokinins, ethylene, abscisic acid, and gibberellins, produced and used in a living plant, or in the produce thereof.

C. Request for Comment

1. *Hypersensitive response*. EPA solicits comment on whether the substances involved in the hypersensitive response meet the proposed criteria and act primarily by affecting the plant. EPA requests comment on whether the language it proposes in this supplemental document adequately describes substances involved in the hypersensitive response.

2. *Functionally modified from the source*. EPA solicits comment on whether the language it has proposed adequately addresses its concern that the genetic material not be functionally modified from the source. EPA solicits comment on whether this language effectively ensures that the genetic material may not be so modified that it has a significantly different specificity or function in the recipient plant than it did in the source plant, yet permits modifications that may be needed to

achieve correct expression, but which have no significant effect on the specificity or function of the pesticidal substance.

3. *Plant hormones*. EPA solicits comment on whether the proposed definition of plant hormone appropriately describes this group of plant substances, and whether these substances act primarily by affecting the plant.

EPA solicits comment on whether plant hormones present a low probability of risk, particularly in light of the NAS report statement that plant hormones ''often cause multiple changes in plants, including changes in secondary metabolites that might be toxic'' (Ref. 13 at 133).

EPA also specifically solicits comment on the NAS statement that ''there is a need to consider separately the impact of plant hormones on nontarget species and the potential for the genes that code for these substances to move to feral populations of weedy relatives of the crop, where they could increase recipient plants' fitness'' (Ref. 13 at 133). In light of this NAS statement, EPA specifically solicits information supporting the broad exemption that EPA proposed in 1994 for plant-incorporated protectants that act by primarily affecting the plant. EPA also requests comment on whether there are subgroups within this category of plant-incorporated protectants for which information exists supporting a finding that the products present a low probability of risk. Commenters are encouraged to submit such information to the Agency.

EPA also solicits comment on the comment received in response to the 1994 proposal that favored exemption of plant hormones except when there is clear indication of unreasonable adverse effects to the plants as can occur in some plant diseases mediated by microorganisms (Ref. 17, for example). The Agency cannot determine the direct relevance that these pathogenic effects would have to this specific exemption, and requests additional information.

4. *Are there subgroups of this category meeting the FFDCA section 408(c) exemption standard*? A plant-incorporated protectant in or on food cannot be exempted from FIFRA requirements unless an exemption from the FFDCA section 408 requirement of a tolerance has been issued for the residues of the plant-incorporated protectant in or on food. If a plant-incorporated protectant is not used in a crop used as food (e.g., the plant-incorporated protectant is produced and used in an ornamental plant), the FFDCA section 408 requirements do not need to be considered when determining whether the plant-incorporated protectant can be exempted from FIFRA requirements. However, if a plant-incorporated protectant is used in a crop used as food (e.g., the plant-incorporated protectant is produced and used in corn), the FFDCA section 408 requirements must be considered when determining whether the plant-incorporated protectant can be exempted from FIFRA requirements. To be considered for full exemption from FIFRA requirements, exemptions from the FFDCA requirement of a tolerance must exist for all of the residues. (See Unit VII.D.1.iv. of the companion document published elsewhere in this issue of the **Federal Register** on regulations for plant-incorporated protectants under FIFRA for additional details).

When EPA proposed in 1994 to exempt from FIFRA requirements plant-incorporated protectants that act primarily by affecting the plant, it did not, because of the broad range and variety of plant-incorporated protectants comprising this category, propose a companion proposal exempting residues of the substance portion of plant-incorporated protectants in this category from the FFDCA section 408 requirement of a tolerance. The Agency would also be interested in comments that describe subgroups of plant-incorporated protectants in this category that would meet the FFDCA section 408(c) standard for an exemption. EPA will treat such comments as a petition for a tolerance exemption pursuant to FFDCA section 408(d); commenters therefore are encouraged to review sections 408(b)(2), (c) and (d) in preparing their comments.

VII. Documents in the Official Record

As indicated in Unit I.B.2., the official record for this supplemental proposal has been established under docket control number OPP–300370B, the public version of which is available for inspection as specified in Unit I.B.2.

A. References

The following books, articles, and reports were used in preparing this supplemental proposal and were cited in this document by the number indicated:

1. USDA/APHIS. 1987. Plant pests; Introduction of genetically engineered organisms or products; Final rule. (52 FR 22891, June 16, 1987).

2. USDA/APHIS. 1993. Genetically engineered organisms and products; Notification procedures for the introduction of certain regulated articles; and petition for nonregulated status; Final rule. (58 FR 17044, March 31, 1993).

3. USDA/APHIS. 1997. Genetically engineered organisms and products; Simplification of requirements and procedures for genetically engineered organisms. (62 FR 23945, May 2, 1997).

4. EPA. Joint meeting of the EPA Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP), Subpanel on Plant-pesticides and the EPA Biotechnology Science Advisory Committee (BSAC), Subcommittee on Plant-Pesticides. January 21, 1994. Final report.

5. Hansen, M. and J. Halloran. In a letter dated February 22, 1995 on docket numbers OPP–300367 through 300371.

6. International Food Biotechnology Council. 1990. Biotechnologies and food; Assuring the safety of foods produced by genetic modification. *Regulatory Toxicology and Pharmacology*. Vol. 12. Academic Press. New York, New York.

7. Wilks, H. M., A. Cortes, D. C. Emery, D. J. Halsall, A. R. Clarke, and J. J. Holbrook. 1992. Opportunities and limits in creating new enzymes. *Enzyme Engineering XI*. Edited by D.S. Clark and D. A. Estell. Annals of the New York Academy of Sciences. Vol. 672. The New York Academy of Sciences. New York, New York.

8. Rissler, J. and M. Mellon. In a letter dated January 23, 1995, on docket control numbers OPP–300367 through OPP–300371.

9. EPA issue paper. 1994. FIFRA: Benefit and environmental risk considerations for inherent plant-pesticides.

10. Laurila, J., I. Lasko, J. P. T. Valkonen, R. Hiltunen, and E. Pehu. 1996. Formation of parental type and novel glycoalkaloids in somatic hybrids between Solanum brevidans and S. tuberosum. *Plant Science*. 118:145–155.

11. Linder, C. R. Long-Term Introgression of Crop Genes into Wild Sunflower Populations. *Theoretical Applied Genetics*. 87:339–347. 1998.

12. Goldburg, R. In a letter dated February 6, 1995, on docket control number OPP–300370.

13. National Research Council. 2000. Genetically Modified Pest-Protected Plants: Science and Regulation. (Prepublication copy). National Academy Press. Washington DC.

14. Cook, R. J. and C. O. Qualset. 1996. (Eds) Appropriate oversight for plants with inherited traits for resistance to pests. Institute of Food Technologists. http://www.Info&ift.org.

15. EPA. 2000. Economic analysis of the plant-incorporated protectant regulations under the Federal

Insecticide, Fungicide, and Rodenticide Act.

16. EPA. 2000. Summary of public comments and EPA response on issues associated with plant-incorporated protectants for dockets listed in OPP–300368, OPP–300368A, OPP–300369, OPP–300369A, OPP–300370, OPP–300370A, OPP–300371, and OPP–300371A.

B. Additional Information

The following additional sources of information are included in the complete official record for this rulemaking:

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) (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–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–30069A 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–300368B for the companion document entitled ''Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues Derived From Sexually Compatible Plants of Plant-Incorporated Protectants (Formerly Plant–Pesticides)'' (FRL–6057–6) published elsewhere in this issue of the **Federal Register**.

The docket identified by the docket control number OPP–300371B for the companion 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)'' (FRL–6057–5) published elsewhere in this issue of the **Federal Register**.

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)'' (FRL–6057–7) published elsewhere in this issue of the **Federal Register**.

The docket identified by the docket control number OPP–300370B for this document (FRL–6760–4).

Also included in the complete official record for this document are:

1. Public comments submitted in response to the proposals and supplemental documents cited in the Unit III.B. In addition, comments received subsequent to the close of the comment period for the 1994 proposal have been included in the record for this supplemental proposal. This includes a report entitled ''Appropriate Oversight for Plants with Inherited Traits for Resistance to Pests'' (Ref. 14), as well as the NAS report (Ref. 13).

2. Reports of all meetings of the Biotechnology Science Advisory Committee and the FIFRA Science Advisory Panel pertaining to the development of the final rule for plant-incorporated protectants published in companion documents elsewhere in this issue of the **Federal Register**.

3. The Economic Analysis of the final rule for plant-incorporated protectants published in companion documents elsewhere in this issue of the **Federal Register** (Ref. 15) and supporting documents.

4. Support documents and reports.

5. Records of all communications between EPA personnel and persons outside EPA pertaining to this supplemental proposal. (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.

7. The response to comments documents pertaining to actions taken by the Agency on dockets OPP–300368, OPP–300368A, OPP–300369, OPP–300369A, OPP–300370, OPP–300370A, OPP–300371, and OPP–300371A (Ref. 16).

VIII. Regulatory Assessment Requirements

This action merely announces the availability of and requests comments on additional data and/or information related to a proposed rule that previously published in the **Federal Register** of November 23, 1994 (59 FR 60519). As such, the regulatory assessment requirements imposed on rulemakings do not apply to this supplemental proposal. Nevertheless, since there have been several revisions to the regulatory assessment mandates that are imposed on rulemakings, the Agency welcomes your comments on the following determinations.

Should the Agency finalize an exemption under FFDCA section 408, and not impose any other requirements, such an action would not 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), nor would it 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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

Such an action would only directly affect growers, food processors, food handlers and food retailers, not States. It would not impose any enforceable duty or contain any unfunded mandate, and would not otherwise significantly or uniquely affect small governments as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). It would not require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998). Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November

6, 2000), which took effect on January 6, 2001, revokes Executive Order 13084 as of that date. EPA developed this rulemaking, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13084. EPA does not expect its analysis to change, and will fully comply with the requirements of Executive Order 13175 before promulgating any final rules. For the same reasons, EPA does not expect these proposed actions to have any substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). Such an action would not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

Such an action would not require a regulatory flexibility analysis under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), because an exemption from the requirement of a tolerance under FFDCA section 408 would not adversely affect any small entities.

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 this action is not expected to affect energy supply, distribution, or use.

For information about the applicability of the regulatory assessment requirements to the previously published proposed rule, please refer to the discussion in Unit XI. of that document (59 FR at 60533).

List of Subjects in 40 CFR Part 174

Environmental protection, Agricultural commodities, Pesticides and pests, Plants.

Dated: July 12, 2001.

Christine T. Whitman,

Administrator.

[FR Doc. 01–17984 Filed 7–16–01; 11:42 am]

BILLING CODE 6560–50–S

Federal Register

Thursday,
July 19, 2001

Part V

Department of Education

Office of Elementary and Secondary Education and the Office of Vocational and Adult Education; Smaller Learning Communities Grant Program; Notice

DEPARTMENT OF EDUCATION

Office of Elementary and Secondary Education and the Office of Vocational and Adult Education—Smaller Learning Communities Grant Program

AGENCY: Department of Education.

ACTION: Notice of proposed priorities, application requirements, and selection criteria for fiscal year 2001.

SUMMARY: The Acting Deputy Assistant Secretary for Elementary and Secondary Education and the Deputy Assistant Secretary for Vocational and Adult Education announce proposed priorities, application requirements, and selection criteria for the Smaller Learning Communities (SLC) grant program for fiscal year FY 2001.

Estimated Available Funds: $125,000,000

Note: The Secretary is authorized to reserve $7,500,000 from these funds for peer review, evaluation, technical assistance, outreach, and product dissemination activities. These activities are designed to support the local grants, evaluate the success of the program, and help ensure the dissemination and replication of best practices to schools nationwide.

DATES: We must receive your comments by August 20, 2001.

ADDRESSES: All comments concerning these proposed priorities, application requirements, and selection criteria should be addressed to Diane Austin, U.S. Department of Education, Office of Elementary and Secondary Education, 400 Maryland Avenue, SW, Room 5C149, Washington, DC 20202. Comments may be sent through the Internet at: *smallerlearningcommunities@ed.gov.* You must include the term ''Smaller Learning Communities Grant Program'' in the subject line of your electronic message.

If you want to comment on the information collection requirements you must send your comments to the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble. You may also send a copy of these comments to the Department representative named in this section.

FOR FURTHER INFORMATION CONTACT: Diane Austin, Smaller Learning Communities Grant Program, U.S. Department of Education, 400 Maryland Avenue, SW, Room 5C149, Washington, DC 20202–6200, (202) 260–1280. Fax: (202) 260–8969. Email: *smallerlearningcommunities@ed.gov.* You may also visit our website at: *www.ed.gov/offices/OESE/SLCP.* Individuals who use the telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the contact person listed above.

Note: This notice does not solicit applications. A notice inviting applications under this competition will be published in the **Federal Register** concurrent with or following the publication of the final priorities, application requirements, and selection criteria. We will determine the final priorities after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing or funding additional priorities, subject to meeting applicable rulemaking requirements.

SUPPLEMENTARY INFORMATION:

Background

The Smaller Learning Communities grant program is authorized under section 10105 of part A of title X of the Elementary and Secondary Education Act of 1965 (ESEA) (20 U.S.C. 8005). Title X, Part A authorizes the Secretary to support nationally significant programs and projects to: (1) Improve the quality of education; (2) assist all students in meeting challenging State content standards; and (3) contribute to achieving National Education Goals.

The purpose of the Smaller Learning Communities Program is to support the implementation or expansion of small, safe, and successful learning environments in large high schools through competitive grants to local educational agencies (LEAs). LEAs may apply on behalf of large high schools, including large high schools funded by the Bureau of Indian Affairs (BIA schools). For the purposes of this program, a large high school is defined as a school that includes grades 11 and 12 and enrolls at least 1,000 students in grades 9 and above.

Strategies for recasting large schools as a set of small learning communities are included in the Conference Report for the Consolidated Appropriations Act, 2000 [Pub. L. 106–113, H.R. Conference Report No. 106–479, at 1240(1999)]. Such strategies include:

(1) Establishing small learning clusters, ''houses,'' career academies, magnet schools, or other approaches to creating schools within schools;

(2) Block scheduling;

(3) Personal adult advocates, teacher advisory systems, and other mentoring strategies;

(4) Reducing teaching loads; and

(5) Other innovations designed to create a more personalized high school experience for students and improve student achievement.

In FY 2000, Congress appropriated $45 million for the SLC program, of which the Department awarded $42.3 million in support of 149 grants to LEAs. The Secretary awarded 84 one-year planning grants and 65 three-year implementation grants. A total of 349 schools, serving over 450,000 students, benefited during the first year of the program. The Secretary reserved the remaining $2,250,000 to fund national leadership activities.

Congress appropriated $125 million for this program in fiscal year 2001. The Administration is not requesting funds for the Smaller Learning Communities program in fiscal year 2002. Rather, the Administration is proposing a new Choice and Innovation State Grants program under which States and LEAs would have greater flexibility in using funds for activities, such as the creation of smaller learning communities, that will lend to educational reform and improvement.

The Secretary intends to share program information and provide grant-writing technical assistance on an as needed basis. Potential applicants are encouraged to review the Frequently Asked Questions section of the program's website at: *www.ed.gov/offices/OESE/SLCP.* Written questions may be submitted through the Internet at: *smallerlearningcommunities@ed.gov.* Details on any other outreach activities will be included as part of the final application package and posted on the program's website at the address listed above.

Priorities

The goal of the Smaller Learning Communities program is to ensure that high schools are safe, nurturing, and effective environments where all students feel known, supported, and motivated to succeed in post secondary education and chosen careers. The proposed priorities authorize the Department to give preference to those applicants that have the greatest need and the capacity to create more personalized learning environments.

Competitive Priorities

Under 34 CFR 75.105(c)(2)(i), the Secretary proposes to give preference to applications that meet one or both of the following two competitive priorities. Where applicable, these points would be in addition to any points the application earns under the selection criteria for this year's grant competition.

Proposed Competitive Priority 1—Low-Performing Schools

The Secretary proposes to award up to five (5) additional points to applicants that provide a comprehensive action plan for turning around low-performing schools in their district. Low-performing schools can be identified by local and State educational agencies under section 1116 of the Elementary and Secondary Education Act. In addition, for the purposes of this program, States and LEAs that have their own established criteria for identifying low-performing schools may use those criteria to meet the competitive priority.

To receive any points under this competitive priority, LEAs, applying on behalf of a low-performing school(s), must provide evidence of their schools' designation. The applicant's plan must reflect its understanding of the research on effective strategies for turning around low-performing schools and describe how the research has been incorporated into its plan for creating a smaller learning community. The application must also both include (1) a plan to build partnerships with technical assistance providers, foundations, or other organizations engaged in turning around low-performing schools; and (2) document how the applicant will use other resources, particularly other Federal resources, in its efforts to improve student achievement.

Proposed Competitive Priority 2—Current Planning Grantees

The Secretary proposes to give preference to applicants that are recipients of planning grants awarded in program year 2000 if they provide evidence of the completion of an SLC implementation plan. LEAs awarded planning grants must produce viable implementation plans. In the case of otherwise evenly scored applicants, the competitive preference shall be the deciding factor.

Application Requirements

A discussion of each proposed requirement follows:

A. Eligible Schools

We propose that to be considered for funding, LEAs must include the name(s) of the eligible school(s) and the number of students enrolled in each school. Enrollment must be based upon data from the current school year or data from the most recently completed school year. LEAs applying on behalf of schools that are being constructed and do not have an active student enrollment at the time of application are not eligible under this program.

Rationale

While the legislation clearly addresses the requirements for eligibility, it does not require LEAs to identify specifically the schools that will benefit from a grant. We propose that each applicant include enrollment data supporting the eligibility of each school. This will enable the Department to determine if each school identified in an application meets the proposed definition of a large high school.

B. Types of Grants

Since the Administration is not requesting funds for the Smaller Learning Communities program in fiscal year 2002, the Secretary proposes to award only implementation grants under this year's competition. LEAs that have a developed plan in place are encouraged to apply for an implementation grant. Further, LEAs with schools that have existing smaller learning communities may apply for an implementation grant if they wish to expand their SLC efforts. Implementation grants will be funded for a three-year project period.

Note: Understanding the unique complexities of implementing a ''transformational'' program requiring changes in the nature of instruction and school culture that impacts the physical design, organization, curriculum, and teacher preparation, the Secretary anticipates awarding the entire grant amount for implementation projects at the time of the initial award. This will provide the applicant with the capacity to carry out effectively the comprehensive long-term activities involved in model development, documentation, evaluation, and dissemination of products and practices developed through the Federal grant.

C. Award Ranges

For a three-year implementation grant, the Secretary proposes that LEAs may request, on behalf of a single school, $250,000 to $500,000 per project. LEAs applying on behalf of a group of eligible schools may request up to $2,500,000 per implementation grant. As this program is designed to finance direct student services and local redesign and improvement efforts, districts must stay within the minimum and maximum school allocations when determining their group award request. Therefore, in order to ensure sufficient implementation funds at the local level, LEAs may not request funds for more than 10 schools under a group application.

The chart below provides ranges for award requests under the implementation grant:

Number of schools in LEA application	Award ranges
One School	$250,000–$500,000
Two Schools	500,000–1,000,000
Three Schools	750,000–1,500,000
Four Schools	1,000,000–2,000,000
Five Schools	1,250,000–2,500,000
Six Schools	1,500,000–2,500,000
Seven Schools	1,750,000–2,500,000
Eight Schools	2,000,000–2,500,000
Nine Schools	2,250,000–2,500,000
Ten Schools	2,500,000

To ensure maximum flexibility and competitiveness, LEAs may submit multiple applications targeting distinct schools within each application. Schools that benefited from FY 2000 implementation awards are not eligible to receive additional support under this competition. The total amount an LEA may receive through any combination of awards made under this program may not exceed 5 million.

Rationale

By establishing grant award ranges and maximum LEA award amounts, the Department will be able to fund a much larger number of grants, ensure maximum geographic distribution, and encourage implementation of a diverse range of SLC strategies. The proposed minimum and maximum award amounts should provide sufficient funding for direct services to students and for school-based implementation activities. The Department determined these amounts in consultation with other Federal programs and private organizations with experience in developing and implementing SLCs. Applicants must be fully committed and prepared to undertake the activities described in the application.

D. Page Limit for the Application Narrative

We strongly recommend that applicants limit the narrative section of the application to the equivalent of no more than 25 double-spaced pages using the following standards:

(1) A page is 8.5″ x 11″, on one side only;

(2) The page limit includes all narrative, titles, headings, footnotes, quotations, references, and captions, as well as charts, tables, figures, and graphs. Charts, tables, figures, and graphs may be single-spaced;

(3) The font should be 11-point or larger;

(4) The page limit does not apply to the Application for Federal Education Assistance Form (424); the Budget information Form (ED 524) and attached itemization of costs; any other required or supplementary application forms and

attachments to those forms; the assurances and certifications; or the table of contents and the one page abstract which should precede the narrative section and provide a short description of the project; evidence of competitive priorities; or appendices;

(5) Appendices used should relate directly to the selection criteria and project activities. Pages should be numbered.

Rationale

In previous competitions successful applicants have demonstrated that they can successfully describe their programs within this page limit.

E. Reporting Requirements and Expected Outcomes

We propose that to be eligible for an implementation grant, applicants must describe in their proposals for funding their:

(a) Project objectives;

(b) Measures of student outcomes and performance; and

(c) Indicators to gauge progress toward meeting project objectives.

In addition, the Secretary proposes to require that applicants for implementation grants have, or will have, a data collection system with the capacity to produce annual performance reports throughout the project period of the grant. These reports will document the grantee's yearly progress toward expected project objectives. The Secretary will use these reports to measure the success of the grantee's project, as well as the effects of the Department of Education's Smaller Learning Communities grant program nationwide.

We also propose that applicants submit initial baseline data for each student outcome measure described below. Baseline data should come from either the current or previous school year. Applicants should report this data as part of their narrative in accordance with the evaluation selection criteria. Upon notification of award, grantees will be required to submit student outcome data for three years preceding the baseline year.

Required student outcome measures include:

I. Student Achievement.

(a) The number of students scoring at each proficiency level for each subject measured by a State or district assessment in grades 9–12; and

(b) The number of students taking the SAT and ACT, and their average scores.

II. Academic Rigor and Student Retention.

(a) The number of students who take courses for which they receive both high school and college credit;

(b) The number of students completing high school; and

(c) The overall reported average daily attendance for October.

III. School Climate.

(a) The number of incidents of student violence, and of alcohol and drug use;

(b) The number of expulsions, suspensions, or other serious disciplinary actions; and

(c) The number of students involved in extracurricular activities.

Note: Percentages may be used in place of number of students where appropriate.

F. Definitions

(a) Definitions in EDGAR—Definitions defined in 34 CFR 77.1 are applicable to this program.

(b) Other definitions—The Secretary proposes that the following definitions also apply to this program:

BIA school is a school operated or supported by the Bureau of Indian Affairs.

A *group of schools* is two or more schools that each meet the definition of a large high school.

A *large high school* is an entity that includes grades 11 and 12 and has an enrollment of 1,000 or more students in grades 9 and above.

A *low-performing school* is a school identified by local and State educational agencies under section 1116 of the Elementary and Secondary Education Act. Under current law, any Title I school that has not made ''adequate yearly progress'' over two consecutive years is identified by its LEA for improvement. In addition, for the purpose of this program, States and LEAs that have established criteria for identifying such schools may use their criteria to meet the competitive priority preference.

Selection Criteria

The Secretary proposes that the following selection criteria be used to evaluate applications for new grants under this competition. The maximum score for all of these criteria is 100 points. The maximum score for each criterion or factor under that criterion is indicated in the parentheses. There are not specific point totals for the subcategories within each criterion.

The Secretary proposes utilizing a peer review process in which peer review panels will evaluate the applications using the selection criteria and the associated point values. The Secretary intends to base final funding decisions on the panel review ranking of applications and an acceptable geographic balance between urban and rural grantees.

Implementation Grants

(a) *Need for the project.* (25 points)

In determining the need for the proposed project, the Secretary considers the following factors:

(1) The description and documentation of the targeted schools' need for the services provided and the need for the activities carried out by the proposed project consistent with the social and educational problems and issues generally associated with the impersonal nature of large high schools. Need may consider factors such as: Enrollment; attendance and drop-out rates; incidents of violence, drug and alcohol use, and disciplinary actions; percentage of students who pass graduation exams or local assessments, enroll in advanced level courses, register for college entrance exams, and matriculate into postsecondary institutions or training; percentage of students who have limited English proficiency, who are migrant youth, who come from low-income families, or are otherwise disadvantaged; the applicant's fiscal capacity to fund programs described here without Federal assistance; or other local need factors as described by the applicant.

(2) The nature and magnitude of specific gaps or weaknesses and the extent to which those weaknesses in services, infrastructure, or opportunities have been identified by the applicant and will be addressed by the proposed project.

(b) *Foundation for implementation.* (15 points)

In determining the quality of the implementation plan for the proposed project, the Secretary considers the extent to which the application:

(1) Documents the involvement and support of stakeholders both within the school community (e.g., administrators, staff, students, and parents) and within the greater community (e.g. representatives of institutions of higher education, employers, workforce investment boards, youth councils, and community-based organizations).

(2) Provides clear evidence of teacher involvement and support, particularly of those teachers who will be affected directly by the implementation plan.

(3) Uses research-based findings and outside technical assistance in the proposed restructuring and in determining appropriate strategy(ies) to be implemented.

(c) *Feasibility and soundness of the plan.* (35 points)

In determining the quality of the proposed project, the Secretary considers the extent to which:

(1) The goals and objectives of the smaller learning communities

correspond to identified needs and are written in terms of student outcomes, including academic achievement.

(2) The curriculum and instructional practices within each smaller learning community are aligned with its goals, theme, and emphases, where they exist.

(3) The proposed smaller learning communities intervention(s) will benefit all students in the school and enable them to reach challenging State content standards and performance standards, ensuring their successful completion of high school and preparation for postsecondary education or a career.

(4) Professional development activities offered to teachers, non-instructional school staff, and others are aligned with smaller learning community goals.

(5) The applicant provides a rationale for—

• Identifying grade levels and ages of students to be served by the smaller learning community; and

• The methods and timetable for placing students in the smaller learning community. *Note:* Students are not to be placed according to ability, performance, or any other measure of merit. The Department expects that all students will benefit from the SLC intervention.

(6) The management plan appears capable of achieving the objectives of the proposed project on time and within budget, including:

• The past experience, training, and clearly defined responsibilities of personnel who have key roles in carrying out the project; and

• The timelines and milestones for accomplishing project tasks.

(d) *Quality of the project evaluation.* (15 points)

In determining the quality of the evaluation to be conducted of the proposed project, the Secretary considers whether the applicant has designed an effective method for:

(1) Collecting student performance data, including:

• Required annual performance reports;

• Baseline data (refer to ''Reporting Requirements and Expected Outcomes''), and data for three years preceding the baseline (the latter due upon award); and

• Monitoring and understanding changes in student outcomes for continuous improvement.

(2) Describing, on an annual basis, the progress towards implementing smaller learning communities and implementing related program changes undertaken to make the smaller learning communities safe and successful. This information will be reported in the Annual Performance Report.

(3) Disseminating best practices and products designed under this grant.

(e) *Adequacy of resources.* (10 points)

In determining the adequacy of resources for the proposed project, the Secretary considers the extent to which:

(1) State, local, foundation, and other Federal funds will be used to support the implementation of the plan.

(2) The applicant will limit equipment, administrative costs, and other purchases in order to maximize the amount spent on delivery of services to students.

(3) The applicant demonstrates a commitment to sustaining the project beyond the period covered by the Federal grant.

Paperwork Reduction Act of 1995

This notice contains information collection requirements. Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the Department of Education has submitted a copy of this notice to OMB for its review.

The time required to complete this information collection is estimated to average sixty-five (65) hours per response, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection.

If you want to comment on the information collection requirements, please send your comments to the Office of Information and Regulatory Affairs, OMB, Room 10235, New Executive Office Building, Washington, DC 20503; Attention: Lauren Wittenberg. You may also send a copy of these comments to the Department representative named in the **ADDRESSES** section of this preamble.

We consider your comments on this proposed collection of information in—

• Deciding whether the proposed collection is necessary for the proper performance of our functions, including whether the information will have practical use;

• Evaluating the accuracy of our estimate of the burden of the proposed collection, including the validity of our methodology and assumptions;

• Enhancing the quality, usefulness, and clarity of the information we collect; and

• Minimizing the burden on those who must respond. This includes exploring 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.

OMB is required to make a decision concerning the collection of information contained in this notice of proposed priorities, requirements, and selection criteria between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, to ensure that OMB gives your comments full consideration, it is important that OMB receives the comments within 30 days of publication. This does not affect the deadline for your comments to us on the proposed regulations.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR Part 79. The objective of the executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local government for coordination and review of proposed Federal assistance.

In accordance with this order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

Invitation To Comment

We invite you to submit comments regarding these proposed priorities, proposed selection criteria, and proposed application requirements. To ensure that your comments have the maximum effect in developing the Secretary's final notice of priorities, application requirements, and selection criteria we urge that you clearly identify the specific section of this notice that each of your comments addresses and arrange your comments in the same order as the sections appear in the notice.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from these proposed priorities, selection criteria, application requirements, and guidance. Please let us know of any further opportunities that we should take to reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program. All comments submitted in response to this notice will be available for public inspection, during and after the comment period, in Room 5C141, 400 Maryland Avenue, SW, Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Eastern time, Monday through Friday of each week excluding Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or

print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for these proposed priorities and proposed selection criteria. If you would like to schedule an appointment for this type of aid, you may call (202) 205–8113 or (202) 260–9895. If you use a TDD, you may call the Federal Information Relay Service (FIRS) at (800) 877–8339.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *www.ed.gov/legislation/FedRegister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://access.gpo.gov/nara/index.html.*

(Catalogue of Federal Assistance Number: 84.215L Smaller Learning Communities Grant Program)

Program Authority: 20 U.S.C. 6661 *et seq.*

Dated: July 13, 2001.

Thomas M. Corwin,

Acting Deputy Assistant Secretary for Elementary and Secondary Education.

Robert D. Muller,

Deputy Assistant Secretary for Vocational and Adult Education.

[FR Doc. 01–18073 Filed 7–18–01; 8:45 am]

BILLING CODE 4000–01–P

Federal Register

Thursday,
July 19, 2001

Part VI

Department of Housing and Urban Development

Notice Inviting Applications: Third Round Designation of Seven Urban Empowerment Zones; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4663–N–02]

Notice Inviting Applications: Third Round Designation of Seven Urban Empowerment Zones

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice inviting applications.

SUMMARY: The Community Renewal Tax Relief Act of 2000 authorizes the designation of nine Round III Empowerment Zones (EZs). Seven of the Round III EZs are to be designated in urban areas by the Secretary of HUD. The remaining two Round III EZs are to be designated in rural areas by the Secretary of Agriculture. This Notice invites applications for designation of nominated areas as Empowerment Zones. The designation of the new Empowerment Zones will be made in accordance with the designation process described in this Notice.

Application Due Date: Completed applications (one original and 2 copies) must be submitted no later than September 28, 2001. See below for specific procedures governing the form of application submission (e.g., mailed application or hand delivery). No facsimile (FAX) applications will be accepted for consideration by HUD.

Delivered Applications. Completed applications (one original and two copies) must be submitted no later than 5:00 p.m. eastern time, on September 28, 2001. Up until 5:00 p.m. on the deadline date, completed applications will be accepted at the address and room number specified below.

Mailed Applications. Applications will be considered timely if postmarked on or before September 28, 2001.

Applications Sent by Overnight Delivery. Overnight delivery items will be considered filed on time if received on or before September 28, 2001.

Electronic Submission of Application Information

Information submitted electronically using the RC/EZ On-Line Application System must be submitted not later than 5 pm, Eastern Time on September 28, 2001. This is done by hitting the ''Submit'' button at each appropriate location in the software. The system will not be available after the deadline.

ADDRESSES: *Address for submitting applications.* Completed paper applications (one original and two copies) should be submitted to: Department of Housing and Urban Development, Office of Community Planning and Development, c/o Processing and Control Unit, Room 7255, 451 7th Street, SW, Washington, DC 20410, by mail or hand delivery.

For Application and Other Materials. For a copy of the EZ Round III Application Guidebook, which includes the Nomination Forms and the EZ Round III rule at 24 CFR part 598 (which also implemented EZ Round II), please call the Community Connections Information Clearinghouse at (800) 998–9999. Round III publications are also available on the HUD web site at: http://www.hud.gov/offices/cpd/ezec. Requests for application materials should be made immediately to insure sufficient time for application preparation. Hearing-or speech-impaired persons should use the Federal Information Relay Service telephone number, (800) 877–8339, to obtain application materials.

The Round III publications consist of:

- Urban Application Guide for Empowerment Zones Round III (Application Guide and Nomination forms);
- The Round II and Round III Rule at 24 CFR part 598;
- Tax Incentive Guide for Businesses in Renewal Communities, Empowerment Zones and Enterprise Communities; and
- Federal Programs Guide.

FOR FURTHER INFORMATION CONTACT: For technical questions, contact Lisa Hill, Empowerment Zone/Enterprise Community Initiative, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW, Room 7130, Washington, DC 20410, (202) 708–6339. Hearing-or speech-impaired individuals may call (800) 877–8339 (the Federal Information Relay Service—TTY).

SUPPLEMENTARY INFORMATION:

I. Summary

A. Purpose and Authority

The Community Renewal Tax Relief Act of 2000 (CRTR Act) authorizes, among other things, the designation of nine Round III Empowerment Zones (EZs). Seven of the Round III EZs are to be designated in urban areas by the Secretary of HUD. The remaining two Round III EZs are to be designated in rural areas by the Secretary of Agriculture. The CRTR Act also conforms and enhances the tax incentives for Round I and Round II EZs, and makes the new Round III EZs eligible for these incentives. The availability of the tax incentives is extended to December 31, 2009 for all EZs.

Section 111 of the CRTR Act adds a new subsection (h), which authorizes the designation of nine additional EZs, to section 1391 of Subchapter U of Chapter 1 of the Internal Revenue Code of 1986. Subchapter U governs the designation and treatment of Empowerment Zones, Enterprise Communities, and Rural Development Investment Areas, and provided authorization by separate legislative enactments for the designation of Round I EZs in 1993, and Round II EZs in 1997.

HUD promulgated Round I EZ regulations at 24 CFR part 597 in 1994, and Round II EZ regulations at 24 CFR part 598 in 1998. Separate Round I and Round II regulations were issued because although many of the Round I and II submission requirements, such as the strategic plan, were similar, there were some differences in the authorizing statutes for each Round. For example, the legislation authorizing the Round II designations changed the eligibility and selection criteria from the Round I requirements. Two specific changes in the Round II eligibility criteria were an increase in the size of zones and elimination of the requirement that at least half of the nominated area consist of census tracts with poverty rates of 35 percent. Round II designations were also permitted to except up to three ''developable sites''—parcels that may be developed for commercial or industrial purposes—from satisfying the two poverty rate criteria that otherwise would be applicable, but the size of the area given this special poverty rate treatment was restricted to a total of 2,000 acres.

Unlike the differences in Round I and Round II, the eligibility and selection criteria for the Round III EZs are the same as the criteria that applied to the Round II EZs. HUD, therefore, implemented Round III by making only conforming changes to include references to Round III in part 598. The regulation at 24 CFR part 598 will apply for Round III designations for urban areas as it did for Round II, and this Notice Inviting Applications for Round III urban EZ designation uses the same procedures as the Round II notice published on April 16, 1998 (63 FR 19162), with only the distribution of point values adjusted to reflect HUD's experience in administering the program. The designation of rural areas as EZs will continue to be implemented separately by the Department of Agriculture.

B. Available Resources

The tax benefits that apply to EZs are the following: Tax-exempt bond financing, Empowerment Zone

employment tax credit, welfare-to-work tax credit, work opportunity tax credit, roll over capital gain from the sale or exchange of any ''original zone asset'' where assets are used to purchase a ''replacement zone asset,'' environmental cleanup cost deduction (''brownfields'' tax incentive), and up to $35,000 of additional section 179 (accelerated depreciation) expensing.

II. Application Preparation

A. Notice of Intent To Participate

Applicants should submit a Notice of Intent to Participate form as soon as possible. The Notice should be submitted on the form provided in the EZ Application Guide or on HUD's RC/EZ On-Line Application System. Instructions for gaining access to the system appear on HUD's web page at: www.hud.gov/offices/cpd/ezec. Submission of the Notice of Intent to Participate is not mandatory, but it will ensure that an applicant receives updated information. The Notice of Intent to Participate may be mailed, or submitted by facsimile (FAX). The address for submitting the Notice of Intent to Participate is: U.S. Department of Housing and Urban Development, Ms. Lisa Hill, EZ/EC Team, Room 7130, 451 Seventh St., SW, Washington, D.C. 20410.

The facsimile number is (202) 708–3363 or (202) 401–7615.

B. Application Requirements

1. The application must include an original and two copies of the items listed below. To facilitate review, please submit applications in such a form that they can be taken apart. Loose leaf binders are preferable.

2. The application submitted on behalf of a nominated urban area shall include:

a. Nomination Form Parts I through IV, with the required certifications and written assurances, including assurances that the nominating governments will administer the Empowerment Zone program in a manner which affirmatively furthers fair housing on the bases of race, color, national origin, religion, sex, disability, and familial status (presence of children);

b. A strategic plan which meets the requirements of the 24 CFR part 598, especially the content specified in § 598.215 of the rule; and

c. 1990 census maps showing:

(i) The boundaries of the local government(s); and

(ii) The boundaries of the nominated area, including developable sites, if any.

3. Preferably, the Strategic Plan will contain no more than 75 pages excluding attachments.

4. The application should contain only the necessary documentation. Appendices or additional information extraneous to evaluation components will not be reviewed. Examples of such extraneous information include: Meeting sign-in sheets, and copies of applications for other programs or funds.

C. Strategic Plan Requirements

The Strategic Plan shall conform to the requirements set forth in 24 CFR 598.215, and the criteria stated in this Notice. Requirements set forth in 24 CFR part 598 will be used in the evaluation process.

III. Designation Process

A. General

HUD will accept for processing those nominations meeting the submission deadline stated in this Notice, and the Eligibility Requirements listed in Subpart B of 24 CFR part 598. Nominating procedures are described in Subpart C of 24 CFR part 598.

B. Exceptions

The Secretary may waive a non-statutory provision of 24 CFR part 598 for good cause where it is determined that the application of the provision would result in undue hardship to the applicant.

C. Application Review

A threshold review will be conducted to ensure the application requirements in Section II.B. of this Notice are satisfied, and the applicant meets the eligibility requirements listed below. Applications determined eligible will receive a technical review under the rating factors described in Section IV of this Notice. Specific maximum point scores for each rating factor are listed in Section IV. Applications will be evaluated against the rating factors, then placed in rank order. Evaluation and ranking of applications will be made relative to other applications received.

To review and rate applications, the Department may establish panels including employees of other Federal agencies to obtain certain expertise and outside points of view.

1. Eligibility Requirements

a. To be considered for designation, a nominated urban area, with the exception of areas described below in the Special Rules, must meet all of the eligibility requirements of 24 CFR 598.100.

The only sources of census data that will be used in determining the eligibility of an area are: The 1990 Decennial Census, and information published by the Bureau of Census and the Bureau of Labor Statistics. The boundary of an urban area nominated for designation as an Empowerment Zone must coincide with the boundaries of census tracts. Census tract means a census tract as the term is used by the Bureau of the Census, or, if and only if census tracts are not defined for the area, a block numbering area.

b. A nominated urban area, with the exception of areas described below in the Special Rules, must demonstrate poverty, unemployment and general distress, as described in 24 CFR 598.110. In addition, each nominated area must satisfy the specific poverty rate criteria in 24 CFR 598.115.

c. *Special Rules.* (i) A nominated area in Alaska or Hawaii is deemed to satisfy the criteria of distress, size, and poverty rate detailed in 24 CFR 598.100(b), (c), (d), and (f), and § 598.110 if, for each census tract or block numbering area within the nominated area, 20 percent or more of the families have income that is 50 percent or less of the statewide median family income (as determined under section 143 of the Internal Revenue Code).

(ii) An area within an Indian reservation (as defined in section 168(j)(6) of the Internal Revenue Code) may be included in an area nominated as an Empowerment Zone by State and local governments. An area completely within an Indian reservation may be nominated by the reservation governing body, and in that case, the area is treated as if it also were nominated by a State and a local government. Where two or more governing bodies have joint jurisdiction over an Indian reservation, the nomination of a reservation area must be a joint nomination.

(iii) Any urban area nominated by an Economic Development Corporation chartered by the State in which it is located or by the District of Columbia shall be treated as nominated by a State and a local government.

2. Technical Review

a. *General.* The technical review will evaluate the quality of the application against the following rating factors:

(i) Quality of the Strategic Plan; and

(ii) Quality of the Commitments made in connection with the Strategic Plan.

The criteria against which HUD will measure these factors, and the maximum points that will be awarded for each factor are described below in Section IV. An application may receive up to 100 total points.

b. *Corrections to Deficient Applications.* HUD will notify an applicant in writing, or by FAX, of any technical deficiencies in the application, and HUD will maintain a log of such communications.

The notification will specify the date by which HUD must receive the applicant's correction of all technical deficiencies, which shall be within 14 calendar days from the date of HUD's notification. If the fourteenth day falls on a Saturday, Sunday, or holiday, the correction must be received by HUD on the next business day. The date and time of receipt of corrections by HUD shall be determined in the same way as the receipt of the application.

Technical deficiencies relate to items that:

(i) Are not necessary for HUD review under the rating factors; and

(ii) Would not improve the substantive quality of the proposal. Examples of technical deficiencies would be a failure to submit proper certifications or failure to submit an application containing an original signature by an authorized official.

If any of the items identified in HUD's written notification of technical deficiencies are not corrected and submitted within the correction period, the application will be ineligible for further consideration.

c. *Clarification of Application and Request for Additional Information.* The Department may contact an applicant to obtain clarification of information submitted in an application. Clarification may include, for example, a request for an applicant to submit additional information to ensure HUD's understanding of the terms of a submitted application. In obtaining clarifying information, the Department may contact an applicant by telephone or in person. The Department will conduct all requests for clarification from an applicant according to uniform procedures and will document all requests.

In addition, the Department reserves the right to conduct independent site inspections of proposed EZ/EC sites to accurately rate and rank an applicant's application under the selection criteria provided in this Notice. Should HUD decide to conduct site visits, it will visit sites according to uniform procedures. The Department will document site visit findings.

HUD employees involved in the review of applications and the making of designation decisions will refrain from providing advance information to any person (other than an authorized employee of HUD) concerning designation decisions, or from otherwise giving any applicant an unfair competitive advantage.

D. Designation Announcements

Designations will be made before January 1, 2002. The nominated urban areas designated as Empowerment Zones will be published in the **Federal Register**.

IV. Designation Rating Factors

In choosing among nominated areas eligible for designation, HUD will consider the following factors:

- Quality of the Strategic Plan; and
- Quality of Commitments made in connection with the Strategic Plan.

The following chart identifies the points that will be assigned to each rating factor. The criteria HUD will use to rate the applications on the factors follow the chart.

RATING FACTORS

	Points
Strategic plan	
Vision/Values	5
Community Assessment	5
Goals/Strategies	10
Implementation Plan	
Projects & Programs	10
Tax Incentive Utilization Plan	30
Developable Sites (optional)	
Governance Plan	5
Community Performance Assessment	5
Strategic Planning Process	5
Total	75
Quality of Commitments	
Resources leveraged and documented	25
Total	100

A. Quality of the Strategic Plan (Maximum Points: 75)

The strategic plan must be developed in accordance with four key principles, described in 24 CFR 598.215: Strategic vision for change, community-based partnerships, economic opportunity, and sustainable community development. The elements required in the strategic plan reflect the key principles. Innovation and creativity are encouraged in fulfilling all elements of the plan.

1. Vision and Values (Maximum Points: 5)

This process should articulate a vision for the future and include a graphic representation for the future physical appearances, land use patterns, and qualities of the community. To improve the quality of the visioning process, the community should reach out to local citizens and encourage participation in the visioning process. Explain how the vision creates economic opportunity, encourages self-sufficiency, and promotes sustainable community development. HUD will consider the extent to which this element:

a. States a clear vision for the future;

b. Develops the foundation upon which the goals are established and specific projects and programs are based;

c. Demonstrates collaboration of the community's diverse stakeholders in arriving at its vision and values statement;

d. Provides an effective vision for the community's long-term transformation; and

e. Exhibits innovation and creativity.

2. Community Assessment (Maximum Points: 5)

a. *Assessment of problems and opportunities:* In order to be considered for Empowerment Zone status the nominated area must be one of pervasive poverty, unemployment and general distress as prescribed by 24 CFR 598.110. The general rule is that 90% of the area's census tracts must have a poverty rate of at least 25%. In addition to meeting the minimum criteria for designation, a full account of community and regional assets and problems should be made. Baseline data should be collected to which outcomes can be compared and success measured. One important area to document is the state of local infrastructure. This includes housing, roads, transportation, water, sewer, solid waste, sidewalks, street lights, drainage, open space, and bandwidth. The state of local services is also crucial such as schools, police, fire, child care, health care, and other social services. The state of human and economic development should be documented, and barriers noted.

b. *Resource analysis:* An assessment of the resources available to the community should be made, including potential resources outside the nominated area, to address identified problems and needs and maximize opportunities that exist within the community. Such resources may include financial, technical, human, cultural, educational, leadership, volunteerism, communications, transportation and commerce centers, rail and mass transit linkages, redevelopable land, public space, infrastructure, and other community and regional assets that form the basis for the formulation and implementation of the strategic plan. (2000 acres of

developable sites outside the zone can be included.)

3. Goals (Maximum Points: 10)

This element describes the comprehensive set of goals to be achieved over the program period, along with the strategies that will be used. In evaluating this element, HUD will consider the extent to which:

a. The goals serve as the framework for specific strategies;

b. The strategies proposed to achieve the strategic plan goals have been effectively described, and demonstrate the link between the goals and proposed projects and programs; and

c. The goals are designed to move the community toward its desired future.

d. *Strategies:* Applicants will be asked to describe how the local plan will be coordinated with regional planning and regional growth management. The plan should include a strategy for re-development with minimal displacement of local residents, and if displacement occurs, how it will be mitigated. Strategies should include how land use and urban design will utilize transportation hubs, incorporate mixed and flexible land use, promote the development of economically mixed and geographically dispersed affordable housing, encourage community land trusts, and promote urban green parks. A strategy is recommended for remodeling and rehabilitation of existing buildings, including modifying existing building, fire, historical preservation, and zoning code requirements if necessary. The plan should explain a process for evaluating the fiscal impact of every project, including a measurement of costs and impacts, compared to revenues and benefits to the community.

4. Implementation Plan (Maximum Points: 55)

This element contains a detailed plan of how the community will implement its strategic plan. The components of the Implementation Plan are: Projects and Programs, Tax Incentive Utilization Plan, a Governance Plan, Community Performance Assessment, and the Strategic Planning Process. These components must provide detailed information for the first 2 years of designation.

a. *Projects and Programs (maximum points: 10).* Due to the lack of grant funding in Round III, this category receives less weight than in Round II, since project will result largely from marketing of tax incentives, and leveraged commitments. Zones should detail how they will leverage local and State funds for specific projects. This element describes the specific projects and programs to be implemented during the first two years of the designation. Timelines and budgets must be provided for the 2-year plan. HUD will evaluate this component considering the extent to which:

(i) The narrative clearly outlines the specific projects and programs that will be implemented, including use of any developable sites, and demonstrates that the projects and programs will result in the achievement of the community's goals;

(ii) Proposed timelines for implementing identified projects and programs are appropriate for the 2-year plan;

(iii) The lead implementing entities are identified;

(iv) Innovative partnerships that ensure maximum community participation and project sustainability are identified;

(v) Proposed budgets are identified for each project or program, and costs and sources of funding are realistic;

(vi) Baselines and proposed measurable outputs and outcomes are provided; and

(vii) The component exhibits innovation and creativity.

b. *Tax Incentive Utilization Plan (maximum points: 30).* This element addresses a significant aspect of the EZ initiative—the use of the business tax incentives available to designated Empowerment Zones to support economic revitalization. EZs need to provide a strong marketing and technical assistance plan to encourage businesses to take advantage of these benefits. If the applicant includes developable sites, this element must include a statement of how developable sites will maximize the use of tax incentives. In evaluating this element, HUD will consider the extent to which the plan:

(i) Provides an effective strategy for integrating the new business tax incentives into the nominated area's business development efforts. The Round III business tax incentives include: Tax-Exempt Bond Financing, Empowerment Zone Employment Tax Credit, Increased Section 179 Deduction, Welfare-to-Work Credit, Environmental Cleanup Cost Deduction (i.e. ''Brownfields Tax Incentive''), and the Work Opportunity Tax Credit. For a description of the tax incentives see the Round III publication, ''Tax Incentive Guide for Businesses in Renewal Communities, Empowerment Zones and Enterprise Communities.''

(ii) Addresses the involvement of all appropriate segments of the community and the extent to which their participation will maximize the use of the business tax incentives;

(iii) Provides a realistic strategy for marketing the incentives; and

(iv) Exhibits innovation and creativity.

c. *Governance Plan (Maximum Points: 5).* This element describes how the strategic plan will be implemented. A leadership development program should be included here, as leadership is extremely important to the success of EZs. Other capacity building plans could be included here as well. A plan for mediation of disputes should also be included. HUD will evaluate the extent to which:

(i) The proposed lead implementing entity, has or will have, the legal status and authority to receive and administer Federal funds;

(ii) The Governance Plan demonstrates that both the lead implementing entity and other key organizations participating in the implementation of the strategic plan have the capacity to implement the plan;

(iii) The proposed composition of governance boards, advisory boards, commissions or similar bodies that will manage strategic plan implementation is representative of the EZ area. The representation of residents and businesses, and the method of selecting members of such boards should provide a clear picture of the use of partnerships;

(iv) The relationships between the governance structure created and local governments, and other major community or regional organizations, such as a metropolitan planning organization, will strengthen the implementation of the strategic plan;

(v) The Governance Plan includes methods by which stakeholders within the Zone will be kept informed about Zone activities and progress in implementing the strategic plan, including an explanation of how the Governance Board will conduct its meetings in accordance with applicable open meetings acts. The community should utilize modern communication techniques and incorporate the Internet in order to enhance the communication and access to information among all stakeholders and participants;

(vi) The Governance Plan will ensure continuing community and grassroots participation in the implementation of the strategic plan and the governance of the Zone's activities; and

(vii) The plan exhibits innovation and creativity.

d. *Community Performance Assessment (maximum points: 5)* This element examines the methods the

community will use to assess its own performance in implementing the strategic plan, and the process it will use to continually review the plan and amend it as appropriate. This information is crucial to the continuing development of the EZ initiative, by learning from what works. It is crucial to measure outcomes as well as outputs. Comparing outcomes to baselines and benchmarks developed in the community assessment will provide a more objective measure of success. In evaluating community performance assessment, HUD will consider:

(i) The process the applicant will use to periodically evaluate its performance;

(ii) The process the applicant will use to modify its strategic plan based on the results obtained in (i);

(iii) The participation of stakeholders in (i) and (ii) above.

5. Strategic Planning Process Documentation (Maximum Points: 5).

This element provides a description of the process the community used to select the boundaries of the proposed Empowerment Zone, including any developable sites, and the process used to prepare the strategic plan. In evaluating this element, HUD will consider the extent to which the documentation:

a. Fully explains how the community participated in choosing the area, including any developable sites; and how the area ultimately nominated was selected over other areas considered;

b. Indicates the specific groups, organizations, and individuals that participated in the production of the plan, describes the history of these groups in the community, and describes their role in creating the plan;

c. Explains how participants were selected and provides evidence that the participants, taken as a whole, broadly represent the racial, cultural, gender and economic diversity of the community; and

d. Identifies two or three topics addressed in the plan that caused the most serious disagreements among participants, and a description of how those disagreements were resolved.

B. Quality of Commitments Made in Connection With the Strategic Plan (Maximum Points: 25)

In 24 CFR 598.210, nominated areas are required to provide written assurances that the Strategic Plan will be implemented. In addition to the certification, it is essential that HUD is able to evaluate the breadth and quality of such commitments.

1. Resources Leveraged (Maximum Points: 10)

In evaluating this element, HUD will consider the extent to which the applicant has leveraged resources, such as funding and/or in-kind services from governmental entities, business, faith-based organizations, non-profit organizations, foundations, educational institutions, and other entities to implement the strategic plan.

2. Resource Commitments Documented (Maximum Points: 15).

The applicant must provide evidence of public and private sector commitments by including letters of commitment, memoranda of understanding or agreement, or other documentation indicating the nature of the participation and the financial and non-financial resources to be contributed. The letters or agreements must be signed by an official of the organization able to make such commitments.

3. Besides the leveraging of finances, EZs need to leverage many different types of commitments including tax and regulatory relief from other levels of government. This could include waivers or reductions in development fees including permit, license, inspection, impact, and utility connection fees. It could also include state and local abatements of taxes on wages, income, sales, personal property, and building improvements. Additional tax and regulatory incentives can be added to the marketing plan for the Tax Incentive Utilization Plan. This section should cover the resources that will be committed to perform cost-benefit studies, and to ensure coordination with regional growth management.

V. Period of Designation

The designation period will commence on the date of designation and will continue until December 31, 2009, except:

1. When the nominating entities have specified an earlier date; or

2. When the designation is revoked by the Secretary.

VI. Findings and Certifications

A. Information Collection Requirements

The information collection requirements contained in this Notice have been approved by the Office of Management and Budget and assigned control number 2506–0148. In accordance with the Paperwork Reduction Act, HUD may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

B. Catalog

The Catalog of Federal Domestic Assistance Program number assigned to this program is 14.244.

C. Environmental Impact

This Notice provides for EZ designations under, and does not alter the environmental requirements of, 24 CFR part 598. Accordingly, under 24 CFR 50.19(c)(5), this Notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321). The environmental review provisions of part 598 are set out in § 598.405.

D. Documentation and Public Access Policy

HUD will ensure that documentation and other information regarding each application submitted pursuant to this Notice are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a 5-year period beginning not less than 30 days after the award of the assistance. Material will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations in 24 CFR part 15.

Dated: July 12, 2001.

Donna M. Abbenante,

Acting General Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 01–18074 Filed 7–18–01; 8:45 am]

BILLING CODE 4210–29–P

Reader Aids

Federal Register

Vol. 66, No. 139

Thursday, July 19, 2001

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids	**202–523–5227**
Laws	**523–5227**
Presidential Documents	
Executive orders and proclamations	**523–5227**
The United States Government Manual	**523–5227**
Other Services	
Electronic and on-line services (voice)	**523–4534**
Privacy Act Compilation	**523–3187**
Public Laws Update Service (numbers, dates, etc.)	**523–6641**
TTY for the deaf-and-hard-of-hearing	**523–5229**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications:

http://www.access.gpo.gov/nara

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access:

http://www.nara.gov/fedreg

E-mail

PENS (Public Law Electronic Notification Service) is an E-mail service for notification of recently enacted Public Laws. To subscribe, send E-mail to

listserv@listserv.gsa.gov

with the text message:

subscribe PUBLAWS-L your name

Use listserv@www.gsa.gov only to subscribe or unsubscribe to PENS. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to:

info@fedreg.nara.gov

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, JULY

34783–35076 2
35077–35364 3
35365–35528 5
35529–35750 6
35751–35888 9
35889–36144 10
36145–36440 11
36441–36694 12
36695–36906 13
36907–37102 16
37103–37396 17
37397–37574 18
37575–37880 19

CFR PARTS AFFECTED DURING JULY

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:
7453 35361
7454 35365
7455 37103
Executive Orders:
13129 (See Notice of June 30, 2001 35363
13220 35527
Administrative Orders:
Memorandum of July 4, 2001 37105
Notices:
Notice of June 30, 2001 35363
Presidential Determinations:
No. 2001–20 of July 2, 2001 37109
No. 2001–21 of July 4, 2001 37111

5 CFR

Proposed Rules:
1650 36494

7 CFR

1 36907
300 37397
301 .....37113, 37401, 37575
353 .....37114, 37397
800 .....35751, 36834
930 .....35889, 35891
1218 37117
1773 .....37405, 37406
Proposed Rules:
274 36495
300 37425
318 37425
319 36892
400 36951
1219 .....36870, 36886

8 CFR

3 37119
Proposed Rules:
211 37429
212 37429

9 CFR

74 37125
94 36695
Proposed Rules:
113 37194
301 35112
303 35112
317 35112
318 35112
319 35112
320 35112
325 35112
331 35112
381 35112
417 35112
430 35112

10 CFR

150 35529
170 35529
171 35529
600 34783
Proposed Rules:
20 36502
50 37432
430 36960

12 CFR

1 .....34784, 36834
5 34792
7 .....34784, 36834
9 34792
23 .....34784, 36834
201 35529
506 37406
552 37407
560 37406
563 37406
566 37406
584 37406
613 36908
Proposed Rules:
7 34855
25 37602
228 37602
345 37602
563 37602
950 36715
952 36715

14 CFR

23 37128
25 .....36697, 37408
39 .....34798, 34800, 34802, 35077, 35371, 35530, 35532, 35533, 35535, 35536, 35538, 35896, 36145, 36146, 36149, 36150, 36152, 36154, 36441, 36443, 36445, 36447, 36449, 36450, 36452, 36453, 36455, 36456, 36699, 37130, 37271
71 .....34807, 35080, 35540, 36700, 36908
73 34808
97 .....37132, 37134
107 37274
108 37330
139 37274
1214 37410
Proposed Rules:
13 37520
39 .....35912, 36215, 36509, 36513, 36516, 36520, 37197, 37435
61 37520
71 .....35914, 35916, 35917

91....37520
119....37520
125....37520
135....37520
142....37520

15 CFR

303....34810
740....36676
742....36676
746....36676
772....36676, 36909
774....36676, 36909

16 CFR

801....35541
802....35541
803....35541

17 CFR

200....35836
211....36457
240....35836
249....36701
270....36156
274....36156

Proposed Rules:

41....34864, 36218
240....34864

19 CFR

24....34813

Proposed Rules:

177....37370

21 CFR

129....35373
165....35373
510....36162
520....35755, 35898
522....35756
556....35544
558....36162

22 CFR

124....35899
125....35899
126....35899, 36834

24 CFR

27....35846
207....35070
290....35846
598....35850
599....35850

Proposed Rules:

1000....37098

26 CFR

Proposed Rules:

1....35112

27 CFR

4....37576
24....37576

Proposed Rules:

4....37609
20....37198

28 CFR

2....37136
16....35374

Proposed Rules:

25....35567

29 CFR

1926....37137
2520....34994, 36368
2560....35886
4022....36702
4044....36702

Proposed Rules:

1904....35113

30 CFR

57....35518

Proposed Rules:

57....35521
250....37611

31 CFR

29....36703
515....36683
538....36683
550....36683
560....36683

32 CFR

668....36711

Proposed Rules:

808....36523

33 CFR

100....34819, 34821, 34823, 34825, 34826, 34828, 37414
117....34829, 35901, 36162, 36163, 36164, 36165, 36466, 37139, 37140, 37578, 37579
165....34829, 34831, 34832, 34834, 34836, 34838, 34839, 34841, 34842, 34844, 34846, 34848, 35080, 35544, 35756, 35758, 36165, 36167, 36168, 37141, 37416, 37580, 37581, 37582, 37584, 37585

Proposed Rules:

100....37200
117....36525, 36527, 36529, 37615
151....36530
153....36530
164....36223

36 CFR

51....35082

Proposed Rules:

219....35918
294....35918
1228....37202

37 CFR

202....37142

Proposed Rules:

1....35763

38 CFR

17....36467
20....35902, 37150

Proposed Rules:

17....36960

39 CFR

111....37151

Proposed Rules:

111....36224

40 CFR

52....35374, 35546, 35903, 35906, 36035, 36170, 36913, 36919, 36921, 37151, 37154, 37418, 37587
60....36473
62....35546
63....35083, 35087, 36173, 36924, 37591
80....37156
81....34994, 36476
82....37752
152....37772
174....37772, 37817, 37830
180....36477, 36481, 37593
261....35379
264....35087
300....34849, 35385, 35547, 36946

Proposed Rules:

9....35572
52....34864, 34878, 35573, 35920, 36226, 36370, 36532, 36542, 36656, 36717, 36963, 36964, 37203, 37204, 37439
60....36547
61....35115
63....35115, 35124, 35126, 35326, 36228, 36836
70....34901
122....35572
123....35572
124....35572
125....35572
141....37617
142....37617
174....37855
180....35921
194....36723
261....36725
264....35124, 35126
265....35126
266....35126
270....35126
300....34906, 35395, 36966, 37439
450....35576

41 CFR

101-6....37728
102-3....37728

42 CFR

Proposed Rules:

100....36735
416....35395
482....35395
485....35395

43 CFR

Proposed Rules:

2....36966

44 CFR

64....36947

45 CFR

Proposed Rules:

46....35576

46 CFR

Ch. IV....37419
310....36175
401....36484

Proposed Rules:

4....36530
25....36223
27....36223
520....37442

47 CFR

1....35387, 36177
36....35107
53....36206
64....36711
73....35107, 35387, 35388, 35760, 36949, 37420, 37599
101....35107

Proposed Rules:

2....35399
20....36989
25....35399
64....35765, 37631
73....35406, 35407, 35767, 35768, 35925, 37442, 37443, 37632, 37633
101....35399

48 CFR

1804....36490
1852....36490

49 CFR

Proposed Rules:

171....35155
571....35177
575....35179

50 CFR

17....35547, 36078
223....37599
300....36208
600....35388
622....35761
635....36711, 37421
648....35566, 36208, 37165
660....35388, 36212
679....35761, 35911, 36213, 36492, 37166, 37167, 37600

Proposed Rules:

17....35580, 36229
32....35193
216....35209
223....35407
600....37634
622....37634, 37635
640....37635
648....36246
679....34852

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 JULY 19, 2001

ENVIRONMENTAL PROTECTION AGENCY

Air pollutants, hazardous; national emission standards:
- Chemical recovery combustion sources; published 7-19-01

Air programs:
- Stratospheric ozone protection—
  - Methyl bromide; quarantine and preshipment applications; exemptions; published 7-19-01

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
- Paraquat, etc.; published 7-19-01

COMMENTS DUE NEXT WEEK

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:
- Alaska; fisheries of Exclusive Economic Zone—
  - Pacific halibut and red king crab; comments due by 7-27-01; published 6-27-01
- West Coast States and Western Pacific fisheries—
  - Hawaii-based pelagic longline restrictions and seasonal area closure, and sea turtle and sea bird migration measures; comments due by 7-27-01; published 6-12-01
  - West Coast salmon; comments due by 7-26-01; published 7-11-01

ENVIRONMENTAL PROTECTION AGENCY

Agency information collection activities:
- Proposed collection; comment request; comments due by 7-23-01; published 5-23-01

Air programs; approval and promulgation; State plans for designated facilities and pollutants:
- California; comments due by 7-26-01; published 6-26-01

Air quality implementation plans; approval and promulgation; various States:
- Colorado; comments due by 7-27-01; published 6-27-01
- Kentucky; comments due by 7-23-01; published 6-21-01
- North Carolina; comments due by 7-27-01; published 6-27-01
- Ohio; comments due by 7-23-01; published 6-22-01
- Pennsylvania; comments due by 7-25-01; published 6-25-01
- Wisconsin; comments due by 7-23-01; published 6-22-01

Air quality implementation plans; √A√approval and promulgation; various States; air quality planning purposes; designation of areas:
- Kentucky and Indiana; comments due by 7-23-01; published 6-22-01

Superfund program:
- National oil and hazardous substances contingency plan—
  - National priorities list update; comments due by 7-23-01; published 6-21-01
  - National priorities list update; comments due by 7-23-01; published 6-21-01

FEDERAL COMMUNICATIONS COMMISSION

Common carrier services:
- Wireless telecommunications services—
  - E911 compatibility; public safety answering points; comments due by 7-25-01; published 7-16-01

HEALTH AND HUMAN SERVICES DEPARTMENT

Food and Drug Administration

Children's Health Act; implementation:
- Clinical investigations of FDA-regulated products; additional safeguards for children; comments due by 7-23-01; published 4-24-01

Food additives:
- Secondary direct food additives—
  - Treatment, storage, and processing of foods; safe use of ozone in gaseous and aqueous phases as antimicrobial agent; comments due by 7-26-01; published 6-26-01

HEALTH AND HUMAN SERVICES DEPARTMENT

Health Care Financing Administration

Medicaid:
- Psychiatric residential treatment facilities providing psychiatric services to individuals under age 21; use of restraint and seclusion; comments due by 7-23-01; published 5-22-01

HOUSING AND URBAN DEVELOPMENT DEPARTMENT

Low income housing:
- Homeownership program; disabled families homeownership assistance; comments due by 7-23-01; published 6-22-01

INTERIOR DEPARTMENT

Surface Mining Reclamation and Enforcement Office

Permanent program and abandoned mine land reclamation plan submissions:
- Louisiana; comments due by 7-27-01; published 6-27-01

LABOR DEPARTMENT

Employment Standards Administration

Fair Labor Standards Act:
- Domestic service; companionship services exemption; comments due by 7-23-01; published 4-23-01

INTERIOR DEPARTMENT

National Indian Gaming Commission

Indian Gaming Regulatory Act:
- Electronic or electromechanical facsimile; definitions; comments due by 7-23-01; published 6-22-01

SECURITIES AND EXCHANGE COMMISSION

Securities:
- Securities Exchange Act of 1934; broker-dealer registration requirements; comments due by 7-26-01; published 6-26-01

TRANSPORTATION DEPARTMENT

Coast Guard

Merchant marine officers and seamen:
- Licensing and manning for officers of towing vehicles; comments due by 7-25-01; published 4-26-01

Ports and waterways safety:
- Miami River and Tamiami Canal, FL; regulated navigation areas and limited access areas; comments due by 7-24-01; published 5-25-01
- Sister Bay, WI; safety zone; comments due by 7-26-01; published 6-26-01

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:
- Airbus; comments due by 7-27-01; published 6-27-01
- Boeing; comments due by 7-23-01; published 5-24-01
- Empresa Brasileira de Aeronautica S.A.; comments due by 7-27-01; published 6-27-01
- Eurocopter France; comments due by 7-23-01; published 5-22-01
- Fairchild; comments due by 7-27-01; published 5-30-01
- Fokker; comments due by 7-27-01; published 6-27-01
- Gulfstream; comments due by 7-23-01; published 6-6-01
- McDonnell Douglas; comments due by 7-23-01; published 5-24-01
- New Piper Aircraft, Inc.; comments due by 7-27-01; published 6-12-01
- Rolls-Royce Corp.; comments due by 7-24-01; published 5-25-01

VOR Federal airways and jet routes; comments due by 7-23-01; published 6-7-01

TREASURY DEPARTMENT

Customs Service

Liquidation of duties:
- Continued dumping and subsidy offset; administrative procedures; comments due by 7-26-01; published 6-26-01

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 202–523–6641. This list is also available online at http://www.nara.gov/fedreg.

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.access.gpo.gov/nara/index.html. Some laws may not yet be available.

S. 657/P.L. 107–19

To authorize funding for the National 4-H Program Centennial Initiative. (July 10, 2001; 115 Stat. 153)

Last List July 9, 2001

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to http://hydra.gsa.gov/archives/publaws-l.html or send E-mail to **listserv@listserv.gsa.gov** with the following text message:

SUBSCRIBE PUBLAWS-L Your Name.

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.