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Contents

Federal Register

Vol. 72, No. 207

Friday, October 26, 2007

Agriculture Department
See Animal and Plant Health Inspection Service
See Forest Service
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 60796

Animal and Plant Health Inspection Service
RULES
Plant-related quarantine, domestic:
Oriental fruit fly, 60759–60760
PROPOSED RULES
Plant-related quarantine, foreign:
Chrysanthemum white rust, 60790

Army Department
NOTICES
Environmental statements; availability, etc.:
Base closures and realignments—
Ft. Benning, GA, 60830

Blind or Severely Disabled, Committee for Purchase From People Who Are
See Committee for Purchase From People Who Are Blind or Severely Disabled

Centers for Disease Control and Prevention
NOTICES
Meetings:
National Institute for Occupational Safety and Health—
Occupational Exposure Sampling Strategies Manual; update, 60851

Centers for Medicare & Medicaid Services
RULES
Medicare:
Organ transplant centers; hospital participation conditions; approval and re-approval requirements
Correction, 60787–60789
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 60851–60853
Medicare:
Deeming authority applications, approvals, denials, etc.—
American Diabetes Association; accreditation, 60856–60857
Medicare and Medicaid:
Deeming authority applications, approvals, denials, etc—
Community Health Accreditation Program, 60853–60854
Joint Commission, 60855–60856
Meetings:
Medicare—
Medicare Education Advisory Panel, 60859–60860
Practicing Physicians Advisory Council, 60858–60859

Coast Guard
RULES
Ports and waterways safety; regulated navigation areas, safety zones, security zones, etc.:
Morgan City-Port Allen Alternate Route, Mile Markers 0.5 to 1.0, LA, 60779–60781

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

Committee for Purchase From People Who Are Blind or Severely Disabled
NOTICES
Procurement list; additions and deletions, 60796–60798
Procurement list; additions and deletions; correction, 60798

Commodity Futures Trading Commission
RULES
Trader reports:
Books and records maintenance, 60767–60771
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 60828–60829

Comptroller of the Currency
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 60930–60932

Consumer Product Safety Commission
RULES
Flammable Fabrics Act:
Carpets and rugs; flammability standards, 60765–60767

Defense Department
See Army Department
NOTICES
Meetings:
Women in Services Advisory Committee, 60829

Employee Benefits Security Administration
NOTICES
Employee benefit plans; individual exemptions:
Gastroenterology and Oncology Associates, P.A. Profit Sharing Plan and Trust et al., 60889–60908

Employment and Training Administration
NOTICES
Adjustment assistance; applications, determinations, etc.:
Benchmark Electronics, Inc., 60908–60909
Fujitsu Ten Corporation of America, 60909
Gemtron Corp. et al., 60909–60911
Lamplight Farms, 60911
Manpower Inc., 60911
Molon Motor and Coil Corp., 60911–60912
National Braid Manufacturing Co., 60912

Energy Department
See Federal Energy Regulatory Commission
See Western Area Power Administration
NOTICES
Meetings:
Advanced Scientific Computing Advisory Committee, 60831

Environmental Protection Agency
RULES
Air quality implementation plans; approval and promulgation; various States:
Michigan, 60781–60786
Pesticide programs:
Biochemical and microbial pesticides; registration data requirements, 60988–61025
Conventional chemicals, biochemical, and microbial pesticides; registration data requirements, 60934–60988
Pesticide data requirements; technical amendments, 61025–61029
Superfund:
National oil and hazardous substances contingency plan priorities list, 60786–60787
PROPOSED RULES
Air quality implementation plans; approval and promulgation; various States:
Michigan, 60793–60794
NOTICES
Committees; establishment, renewal, termination, etc.:
Science Advisory Board, 60844–60845
Environmental statements; availability, etc.:
Agency comment availability, 60845–60846
Agency weekly receipts, 60846–60847
Superfund; response and remedial actions, proposed settlements, etc.:
B&B Manufacturing Site, AL, 60847–60848

Executive Office of the President
See Presidential Documents

Federal Aviation Administration
RULES
Airworthiness directives:
Bell Helicopter Textron, Inc., 60760–60762
Rolls-Royce plc, 60762–60764
Class D airspace, 60764–60765
PROPOSED RULES
Airworthiness directives:
Cessna, 60790–60793
NOTICES
Exemption petitions; summary and disposition, 60927–60928
Meetings:
Aviation Rulemaking Advisory Committee, 60928–60929

Federal Energy Regulatory Commission
NOTICES
Complaints filed:
Southern California Generation Coalition, 60836–60837
Electric rate and corporate regulation combined filings, 60837–60839
Environmental statements; availability, etc.:
Alcoa Power Generating, Inc, et al; public meeting, 60839
Hydroelectric applications, 60839–60842
Meetings:
Colorado Interstate Gas Co.; technical conference, 60842–60843
Applications, hearings, determinations, etc.:
Acacia Natural Gas Corp., 60831
Ameren Illinois Transmission Co., 60831–60832
Brown, D. Tim, 60832
Entergy Gulf States, Inc., 60832
Midcontinent Express Pipeline LLC, 60832–60833
Southeastern Power Administration, 60834
Southern Natural Gas Co., et al., 60834–60835
Southwestern Power Administration, 60835–60836
Trunkline Gas Company, LLC, 60836

Food and Drug Administration
NOTICES
Human drugs:
Exocrine pancreatic insufficiency drug products; continued enforcement discretion, 60860–60862
Reports and guidance documents; availability, etc.:
Impact-resistant lenses; industry guidance, 60862–60863

Forest Service
NOTICES
Environmental statements; availability, etc.:
Smoky Canyon Mine, Panels F and G, Caribou-Targhee National Forest, ID, 60881–60882

Geological Survey
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 60875–60876

Health and Human Services Department
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health
NOTICES
Protection of human subjects:
Institutional Review Board; research categories list; expedited review procedure, 60848–60851

Homeland Security Department
See Coast Guard
See Transportation Security Administration
See U.S. Customs and Border Protection
NOTICES
Secure Fence Act of 2006:
Arizona; construction of physical barriers and roads along U.S. international land border; legal requirements waiver; secretarial determination, 60870

Housing and Urban Development Department
NOTICES
Grants and cooperative agreements; availability, etc.:
Homeless assistance; excess and surplus Federal properties, 60872–60875

Interior Department
See Geological Survey
See Land Management Bureau
See National Park Service
See Reclamation Bureau

International Trade Administration
NOTICES
Antidumping:
Ball bearings and parts from—
France and Italy, 60798–60799
Corrosion-resistant carbon steel flat products from—
Korea, 60799–60800
Frozen warmwater shrimp from—
Various countries, 60800–60801
Polyethylene terephthalate film, sheet, and strip from—
Various countries, 60801–60807
Stainless steel bar from—
Germany, 60807–60808

Stainless steel wire rods from—
India, 60808–60811
Wooden bedroom furniture from—
China, 60812–60814

International Trade Commission
NOTICES
Import investigations:
3G wideband code division multiple access handsets and components, 60887–60888

Labor Department
See Employee Benefits Security Administration
See Employment and Training Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 60888–60889

Land Management Bureau
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 60876–60877
Environmental statements; availability, etc.:
Canyons of the Ancients National Monument, CO; resource management plan, 60877–60879
Richfield, UT; resource management plan, 60879–60881
Smoky Canyon Mine, Panels F and G, Caribou-Targhee National Forest, ID, 60881–60882
Meetings:
Powder River Regional Coal Team, 60882–60883

Monetary Offices
RULES
Operations and procedures:
Misuse of words, letters, symbols, or emblems of United States Mint; civil penalties assessment, 60772–60779

National Institutes of Health
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 60863
Inventions, Government-owned; availability for licensing, 60863–60865
Meetings:
Autoimmune and allergic disorders treatment; licensing and collaborative research opportunities; teleconference, 60865–60866
National Center for Complementary and Alternative Medicine, 60866
National Center for Research Resources, 60867
National Institute of Allergy and Infectious Diseases, 60868
National Institute of Diabetes and Digestive and Kidney Diseases, 60868
National Institute of Mental Health, 60868–60869
National Institute of Neurological Disorders and Stroke, 60867
National Institute on Drug Abuse, 60867–60868
Scientific Review Center, 60869–60870

National Oceanic and Atmospheric Administration
PROPOSED RULES
Fishery conservation and management:
Caribbean, Gulf, and South Atlantic fisheries—
Southern Atlantic states; for-hire fishery control date, 60794–60795
NOTICES
Endangered and threatened species:
Incidental taking—
California/Oregon drift gillnet fishery; fin, humpback, and sperm whales, 60814–60822
Marine mammal permit applications, determinations, etc., 60822–60823
Marine mammals:
Incidental taking; authorization letters, etc.—
U.S. Navy; Mayport, FL; offshore waters full ship shock trial, 60823–60824
Meetings:
Mid-Atlantic Fishery Management Council, 60824–60825
Vessel monitoring systems; approved mobile transmitting units, 60825–60828

National Park Service
NOTICES
Environmental statements; availability, etc.:
Ala Kahakai National Historic Trail, Hawaii; comprehensive management plan, 60883–60885
Environmental statements; record of decision:
Flight 93 National Memorial, PA; general management plan, 60885–60886
Meetings:
National Preservation Technology and Training Board, 60886
Realty actions; sales, leases, etc.:
Alaska, 60886–60887

National Science Foundation
NOTICES
Antarctic Conservation Act of 1978; permit applications, etc., 60912–60913
Meetings:
Integrative Activities Advisory Panel, 60913

Nuclear Regulatory Commission
RULES
Spent nuclear fuel and high-level radioactive waste; independent storage; licensing requirements:
Approved spent fuel storage casks; list, 60760
NOTICES
Meetings; Sunshine Act, 60918
Applications, hearings, determinations, etc.:
Alaska Industrial X-Ray, Inc., 60913–60915
FirstEnergy Nuclear Operating Co., 60916–60918

Presidential Documents
ADMINISTRATIVE ORDERS
Brazil; drug interdiction assistance (Presidential Determination)
No. 2008-3 of October 16, 2007, 61035
Democratic Republic of the Congo; continuation of national emergency (Notice of October 24, 2007), 61043–61045
Palestine Liberation Organization; waiver of statutory provisions (Presidential Determination)
No. 2008-2 of October 11, 2007, 61031–61033
Saudi Arabia; counterterrorism assistance (Presidential Determination)
No. 2008-5 of October 19, 2007, 61041
Trafficking in persons; foreign governments' efforts regarding (Presidential Determination)
No. 2008-4 of October 18, 2007, 61037–61039

Railroad Retirement Board
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 60918–60919

Reclamation Bureau
NOTICES
Meetings:
Managing for Excellence project, 60887

Securities and Exchange Commission
NOTICES
Self-regulatory organizations; proposed rule changes:
Financial Industry Regulatory Authority, Inc., 60919–60922
NASDAQ Stock Market LLC, 60922–60924
New York Stock Exchange LLC, 60924–60925
Options Clearing Corp., 60925–60927

Surface Transportation Board
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 60929
Meetings:
Rail carriers; cost-of-capital determinations; methodology, 60929–60930
Railroad operation, acquisition, construction, etc.:
BNSF Railway Co, 60930

Transportation Department
See Federal Aviation Administration
See Surface Transportation Board

Transportation Security Administration
NOTICES
Transportation Worker Identification Credential Program:
TWIC Enrollment Date; Port of Corpus Christi, TX, 60871

Treasury Department
See Comptroller of the Currency
See Monetary Offices
NOTICES
Boycotts, international:
Countries requiring cooperation; list, 60930

U.S. Customs and Border Protection
NOTICES
Meetings:
Commercial Operations of Customs and Border Protection and Related Homeland Security Functions Departmental Advisory Committee, 60871–60872

Western Area Power Administration
NOTICES
Environmental statements; availability, etc.:
Big Stone II Power Plant and Transmission Project, SD; public hearing, 60843–60844

Separate Parts In This Issue

Part II
Environmental Protection Agency, 60988–61029

Part III
Executive Office of the President, Presidential Documents, 61031–61033, 61035, 61037–61039, 61041

Part IV
Executive Office of the President, Presidential Documents, 61043–61045

Reader Aids

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

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

CFR PARTS AFFECTED IN THIS ISSUE

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

3 CFR

Executive Orders:
13413 (See Notice of October 24, 2007).....61045

Administrative Orders:
Notices:
Notice of October 24, 2007 61045
Presidential Determinations:
No. 2008-2 of October 11, 2007.....61033
No. 2008-3 of October 16, 2007.....61035
No. 2008-4 of October 18, 2007.....61037
No. 2008-5 of October 19, 2007.....61041

7 CFR
301.....60759

Proposed Rules:
319.....60790

10 CFR
72.....60760

14 CFR
39 (2 documents) 60760, 60762
71.....60764

Proposed Rules:
39.....60790

16 CFR
1630.....60765
1631.....60765

17 CFR
18.....60767

31 CFR
92.....60772

33 CFR
165.....60779

40 CFR
9.....60934
52 (2 documents) 60781, 60783
152.....61025
156.....61025
158 (2 documents) 60934, 60988
159.....61025
160.....61025
168.....61025
172.....61025
300.....60786

Proposed Rules:
52 (2 documents) 60793

42 CFR
482.....60787

50 CFR

Proposed Rules:
622.....60794

Rules and Regulations

Federal Register
Vol. 72, No. 207
Friday, October 26, 2007

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

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS–2006–0151]

Oriental Fruit Fly; Addition and Removal of Quarantined Areas in California

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the Oriental fruit fly regulations by removing the Santa Ana area of Orange County, CA, from the list of quarantined areas and removing restrictions on the interstate movement of regulated articles from that area. That action was necessary to remove restrictions that were no longer necessary to prevent the spread of the Oriental fruit fly into noninfested areas of the United States. The Santa Ana area of Orange County, CA, was the last remaining area in California quarantined for Oriental fruit fly. Therefore, as a result of that action, there are no longer any areas in the continental United States quarantined for the Oriental fruit fly.

DATES: Effective on October 26, 2007, we are adopting as a final rule the interim rule published at 72 FR 40061–40062 on July 23, 2007.

FOR FURTHER INFORMATION CONTACT: Mr. Wayne D. Burnett, Domestic Coordinator, Fruit Fly Exclusion and Detection Programs, APHIS, 4700 River Road Unit 137, Riverdale, MD 20737–1234; (301) 734–6553.

SUPPLEMENTARY INFORMATION:

Background

The Oriental fruit fly, *Bactrocera dorsalis* (Hendel), is a destructive pest of citrus and other types of fruit, nuts, vegetables, and berries. The short life cycle of the Oriental fruit fly allows rapid development of serious outbreaks, which can cause severe economic losses. Heavy infestations can cause complete loss of crops.

The Oriental fruit fly regulations, contained in 7 CFR 301.93 through 301.93–10 (referred to below as the regulations), restrict the interstate movement of regulated articles from quarantined areas to prevent the spread of the Oriental fruit fly to noninfested areas of the United States. The regulations also designate soil and a large number of fruits, nuts, vegetables, and berries as regulated articles.

In an interim rule [1] effective and published in the **Federal Register** on November 17, 2006 (71 FR 66831–66833, Docket No. APHIS–2006–0151), we amended the regulations by adding a portion of San Bernardino County, CA, to the list of quarantined areas and restricting the interstate movement of regulated articles from that area. We also amended the definitions of the terms *core area* and *day degrees* and added jujube (*Ziziphus* spp.) to the list of articles regulated for Oriental fruit fly. The November 2006 interim rule was necessary to prevent the spread of Oriental fruit fly into noninfested areas of the United States and to update the regulations to reflect current science and practices.

Comments on the interim rule were required to be received on or before January 16, 2007. We did not receive any comments.

In a second interim rule [2] effective and published in the **Federal Register** on January 22, 2007 (72 FR 2597–2599, Docket No. APHIS–2006–0151), we amended the regulations by adding the Santa Ana area of Orange County, CA, to the list of quarantined areas and restricting the interstate movement of regulated articles from that area. In addition, we removed the portion of San Bernardino County, CA, from the list of quarantined areas and removed restrictions on the interstate movement of regulated articles from that area. We took that action based on trapping surveys conducted by inspectors of California State and county agencies that showed that the Santa Ana area of Orange County, CA, had been infested with the Oriental fruit fly and that the Oriental fruit fly had been eradicated from the quarantined portion of San Bernardino County, CA.

Comments on the interim rule were required to be received on or before March 23, 2007. We received one comment by that date, from a private citizen. The commenter alluded to fruit fly eradication efforts that had occurred in the 1980s, but did not address the interim rule.

Finally, in a third interim rule [3] effective and published in the **Federal Register** on July 23, 2007 (72 FR 40061–40062, Docket No. APHIS–2006–0151), we amended the regulations by removing the Santa Ana area of Orange County, CA, from the list of quarantined areas and removing restrictions on the interstate movement of regulated articles from that area. We took that action based on trapping surveys conducted by inspectors of California State and county agencies that showed that the Oriental fruit fly had been eradicated from the Santa Ana area of Orange County, CA. As a result of that action, there are no longer any areas in the continental United States quarantined for the Oriental fruit fly.

Comments on the interim rule were required to be received on or before September 21, 2007. We did not receive any comments. Therefore, for the reasons given in the interim rule, we are adopting the July 2007 interim rule as a final rule.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

List of Subjects in 7 CFR Part 301

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

[1] To view the interim rules and the comment we received, go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d= APHIS–2006–0151.*

[2] See footnote 1.

[3] See footnote 1.

PART 301—DOMESTIC QUARANTINE NOTICES

■ Accordingly, we are adopting as a final rule, without change, the interim rule that amended 7 CFR part 301 and that was published at 72 FR 40061–40062 on July 23, 2007.

Done in Washington, DC, this 22nd day of October 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–21119 Filed 10–25–07; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150–AI21

List of Approved Spent Fuel Storage Casks: TN–68 Revision 1, Confirmation of Effective Date

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule: confirmation of effective date.

SUMMARY: The Nuclear Regulatory Commission (NRC) is confirming the effective date of October 30, 2007, for the direct final rule that was published in the **Federal Register** on August 16, 2007 (72 FR 45880). This direct final rule amended the NRC's regulations to revise the TN–68 cask system listing to include Amendment No. 1 to Certificate of Compliance (CoC) No. 1027.

DATES: *Effective Date:* The effective date of October 30, 2007, is confirmed for this direct final rule.

ADDRESSES: Documents related to this rulemaking, including any comments received, may be examined at the NRC Public Document Room, located at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jayne M. McCausland, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–6219, e-mail *jmm2@nrc.gov.*

SUPPLEMENTARY INFORMATION: On August 16, 2007 (72 FR 45880), the NRC published a direct final rule amending its regulations at 10 CFR 72.214 to revise the TN–68 cask system listing within the ''List of Approved Spent Fuel Storage Casks'' to include Amendment No. 1 to CoC No. 1027. This amendment modifies the CoC by revising several fuel parameters that include increasing fuel burnup to 60 gigawatts-day/metric ton of uranium, increasing total cask decay heat to 30 kilowatts, increasing maximum average fuel enrichment to 4.7 weight percent uranium-235, and decreasing minimum fuel assembly cooling time to 7 years. Amendment No. 1 will also add up to eight damaged fuel assemblies as authorized contents of the cask and reduce the cask spacing on the storage pad. In the direct final rule, NRC stated that if no significant adverse comments were received, the direct final rule would become final on October 30, 2007. The NRC did not receive any comments on the direct final rule. Therefore, this rule will become effective as scheduled.

Dated at Rockville, Maryland, this 22nd day of October, 2007.

For the Nuclear Regulatory Commission.

Michael T. Lesar,

Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration.

[FR Doc. E7–21143 Filed 10–25–07; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–27496; Directorate Identifier 2005–SW–37–AD; Amendment 39–15238; AD 2007–22–02]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron, Inc. Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final Rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD) for the specified Bell Helicopter Textron, Inc. (Bell) Helicopters. That AD currently requires inspecting each affected tail rotor blade (blade) forward tip weight retention block (tip block) and the aft tip closure (tip closure) for adhesive bond voids, and removing any blade with an excessive void from service. That AD also requires modifying certain blades by installing shear pins and tip closure rivets. This amendment contains the same requirements but expands the applicability to include other part and serial-numbered blades. This AD also clarifies the requirement to re-identify the modified blade by adding ''FM'' after the part number and also requires dynamically balancing the tail rotor. The existing AD was prompted by five occurrences of missing tip blocks or tip closures resulting in minor to substantial damage. This amendment was prompted by the determination that the AD should apply to other affected part and serial-numbered blades. The actions specified by this AD are intended to prevent loss of a tip block or tip closure, loss of a blade and subsequent loss of control of the helicopter.

DATES: Effective November 30, 2007.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 30, 2007.

ADDRESSES: You may get the service information identified in this AD from Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, Texas 76101, telephone (817) 280–3391, fax (817) 280–6466.

Examining the Docket: You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is the Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Michael Kohner, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Certification Office, Fort Worth, Texas 76193–0170, telephone (817) 222–5447, fax (817) 222–5783.

SUPPLEMENTARY INFORMATION: A proposal to amend 14 CFR part 39 by superseding AD 2002–09–04, Amendment 30–12737 (67 FR 22349, May 3, 2002), for the specified Bell model helicopters was published in the **Federal Register** on March 13, 2007 (72 FR 11295). The action proposed: retaining requirements to inspect the tip block and the tip closure for adhesive bonding voids and to remove any blade with an excessive void from service; retaining requirements to modify certain blades by installing shear pins and tip closure rivets in the tip area of the affected blades; expanding the applicability to include more blades and clarifying other requirements.

Since issuing AD 2002–09–04, Bell issued further revisions to Alert Service Bullet (ASB) Nos. 205–00–80, 205B–00–

34, 212–00–111, 412–00–106, and 412CR–00–13, Revision A, dated December 20, 2000. The revisions add blades with a serial number (S/N) prefix of ''A'' or ''AFS'' and number of 11530 to 13594, 13603 to 13618, and also change the ''effectivity'' of the blades. The latest revisions, Revisions D, all dated March 18, 2005, provide an alternative fastener for the blade tip closure rivets installation. The revised ASBs also state that blades with S/N A or AFS–11926, 13351, 13367, 13393, 13400, 13402, 13515, 13540, 13568, 13595 to 13602, 13619, and subsequent will be modified before delivery.

The previously described unsafe condition is likely to exist or develop on other helicopters of these same type designs. Therefore, this AD supersedes AD 2002–09–04 to expand the applicability for the blade part and serial number. This AD also clarifies the requirement to re-identify the modified blade by adding ''FM'' after the part number and also requires dynamically balancing the tail rotor. Because blades, S/N with a prefix of ''A'' or ''AFS'' and a number 11926, 13351, 13367, 13393, 13400, 13402, 13515, 13540, 13568, 13595 to 13602, 13619, and subsequent, will be modified before delivery, we are excluding them from the applicability of this AD.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

The FAA estimates that this AD will affect 281 helicopters of U.S. registry. The required actions will take about 3 work hours per helicopters to inspect certain blades, install the shear pins and tip closure rivets, reidentify the modified blades, and dynamically balance the blade assembly at an average labor rate of $80 per work hour. Required supplies will cost about $35 per helicopter. Based on these figures, we estimate the total cost impact of the AD on U.S. operators to be $77,275.

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12833;

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

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

We prepared an economic evaluation of the estimated costs to comply with this AD. See the AD docket to examine the economic evaluation.

Authority for This Rulemaking

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by removing Amendment 39–12737 (67 FR 22349, May 3, 2002), and by adding a new airworthiness directive (AD), Amendment 39–15238, to read as follows:

2007–22–02 Bell Helicopter Textron, Inc.: Amendment 39–15238. Docket No. FAA–2007–27496; Directorate Identifier 2005–SW–37–AD. Supersedes AD 2002–09–04, Amendment 39–12737, Docket No. 2001–SW–37–AD.

Applicability

Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP helicopters with a tail rotor blade (blade), part number 212–010–750–009 through –129, all serial numbers except serial numbers with a prefix of ''A'' or ''AFS'' and the number 11926, 13351, 13367, 13393, 13400, 13402, 13515, 13540, 13568, 13595 through 13602, 13619, and subsequent assigned numbers, installed, certificated in any category.

Compliance

Within 100 hours time-in-service, unless accomplished previously.

To prevent loss of the forward tip weight retention block (tip block) or aft tip closure (tip closure), loss of the blade, and subsequent loss of control of the helicopter, accomplish the following:

(a) Inspect the tip block and tip closure for voids. Remove from service any blade with a void in excess of that allowed by the Component Repair and Overhaul Manual limitations.

(b) Inspect the tip block attachment countersink screws in four locations to determine if the head of each countersunk screw is flush with the surface of the abrasion strip. The locations of these four screws are depicted on Figure 1 of Bell Helicopter Textron, Inc. Alert Service Bulletins 205–00–80, 205B–00–34, 212–00–111, 412–00–106, and 412CF–00–13, all Revision D, all dated March 18, 2005 (ASB). If any of these screws are set below the surface of the abrasion strip or are covered with filler material, install shear pins by following the Accomplishment Instructions, Part A, Shear Pin Installation paragraphs, of the ASB appropriate for your model helicopter.

(c) Install the aft tip closure rivets, re-identify the modified blade by adding an ''FM,'' and dynamically balance the tail rotor hum assembly by following the Accomplishment Instructions, Part B, Aft Tip Closure Rivet Installation paragraphs, of the ASB appropriate for your model helicopter.

(d) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Manager, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, ATTN: Michael Kohner, Aviation Safety Engineer, Fort Worth, Texas 76193–0170, telephone (817) 222–5447, fax (817) 222–5783, for information about previously approved alternative methods of compliance.

(e) Inspecting certain screws to determine if they are flush with the surface of the abrasion strip, modifying blades by installing shear pins or aft tip closure rivets as necessary, and re-identifying the modified blade shall be done by following Bell Helicopter Textron, Inc. Alert Service Bulletins 205–00–80, 205B–00–34, 212–00–111, 412–00–106, and 412CF–00–13, all Revision D, all dated March 18, 2005. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be

obtained from Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, Texas 76101, telephone (817) 280–3391, fax (817) 280–6466. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(f) This amendment becomes effective November 30, 2007.

Issued in Fort Worth, Texas, on October 10, 2007.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 07–5186 Filed 10–25–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–28976; Directorate Identifier 2007–NE–28–AD; Amendment 39–15244; AD 2007–22–08]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc (RR) RB211 Trent 768–60, 772–60, 772B–60, and 772C–60 Turbofan Engines

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

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) provided by the aviation authority for the United Kingdom to identify and correct an unsafe condition on an aviation product. The MCAI states the following:

This action is necessary following the discovery of IP Compressor Rotor stage 2–3 interstage spacer cracking on an in-service Trent 700 engine. Stress analysis of the damaged rotor has shown a possible threat to the rotor integrity, the cracking therefore presents a potential unsafe condition. The cause of the cracking is currently under investigation.

We are issuing this AD to detect cracks in the stage 2–3 interstage spacer of the intermediate pressure (IP) Compressor Rotor. Cracking of the stage 2–3 interstage spacer could result in an uncontained engine failure and damage to the airplane.

DATES: This AD becomes effective November 13, 2007.

The Director of the Federal Register approved the incorporation by reference of RR service bulletins (SBs) RB.211–72–AE753, Revision 1, dated May 24, 2005, and RB.211–72–AF197, dated December 20, 2006, listed in the AD as of November 13, 2007.

ADDRESSES: You may send comments by any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey, Avenue, SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is the same as the Mail address provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Christopher Spinney, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 16 New England Executive Park, Burlington, MA 01803; e-mail: *christopher.spinney@faa.gov;* telephone (781) 238–7175; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2007–0136, dated May 14, 2007, to correct an unsafe condition for the specified products. The EASA AD states:

This Airworthiness Directive requires inspections for cracks in the stage 2–3 interstage spacer of the IP Compressor Rotor during shop visit.

This action is necessary following the discovery of IP Compressor Rotor stage 2–3 interstage spacer cracking on an in-service Trent 700 engine. Stress analysis of the damaged rotor has shown a possible threat to the rotor integrity, the cracking therefore presents a potential unsafe condition. The cause of the cracking is currently under investigation.

You may obtain further information by examining the EASA AD in the AD docket.

Relevant Service Information

Rolls-Royce plc has issued Service Bulletins RB.211–72–AE753, Revision 1, dated May 24, 2005, and RB.211–72–AF197, dated December 20, 2006. The actions described in that service information are intended to correct the unsafe condition identified in the EASA AD.

FAA's Determination and Requirements of this AD

This product has been approved by the aviation authority of the United Kingdom, and is approved for operation in the United States. Pursuant to our bilateral agreement with the United Kingdom, they have notified us of the unsafe condition described in the EASA AD and service information referenced above. We are issuing this AD because we evaluated all the information provided by the EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. We are issuing this AD to detect cracks in the stage 2–3 interstage spacer of the IP Compressor Rotor. Cracking of the stage 2–3 interstage spacer could result in an uncontained engine failure and damage to the airplane. This AD requires inspecting the stage 2–3 interstage spacer using an eddy current inspection process at every shop visit. You must use the service information described previously to perform the actions required by this AD.

FAA's Determination of the Effective Date

Although no airplanes that are registered in the United States use these engines, the possibility exists that the engines could be used on airplanes that are registered in the United States in the future. The unsafe condition described previously is likely to exist or develop on other RR RB211 Trent 768–60, 772–60, 772B–60, and 772C–60 turbofan engines of the same type design. Therefore, we determined that notice and opportunity for public comment before issuing this AD are unnecessary and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2007–28976; Directorate Identifier 2007–NE–28–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this AD:

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2007–22–08 Rolls-Royce plc: Amendment 39–15244; Docket No. FAA–2007–28976; Directorate Identifier 2007–NE–28–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective November 13, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Rolls-Royce plc RB211 Trent 768–60, 772–60, 772B–60, and 772C–60 turbofan engines. These engines are installed on, but not limited to, Airbus A330 series airplanes.

Reason

(d) This action is necessary following the discovery of IP Compressor Rotor stage 2–3 interstage spacer cracking on an in-service Trent 700 engine. Stress analysis of the damaged rotor has shown a possible threat to the rotor integrity, the cracking therefore presents a potential unsafe condition. The cause of the cracking is currently under investigation.

We are issuing this AD to detect cracks in the stage 2–3 interstage spacer of the IP Compressor Rotor. Cracking of the stage 2–3 interstage spacer could result in an uncontained engine failure and damage to the airplane.

Actions and Compliance

(e) Inspect the IP compressor drum stage 2–3 interstage spacer for cracking at every shop visit as follows:

Inspection In-shop

(1) If the IP Compressor rotor is not removed from the IP Compressor Casing, inspect the IP compressor drum stage 2–3 interstage spacer by borescope in accordance with Rolls-Royce RB211 Propulsion System Alert Non Modification Service Bulletin RB211–72–AE753 revision 1, section 3 Accomplishment Instructions (paragraphs F and G are applicable in revision 1).

(2) If the IP Compressor rotor is removed from the IP Compressor Casing inspect the IP compressor drum stage 2–3 interstage spacer by Eddy Current Inspection in accordance with Rolls-Royce RB211 propulsion System Alert Non Modification Service Bulletin RB211–72–AF197 initial issue, section 3 accomplishment Instructions.

(3) IP compressor drums on which cracking is identified by the above means must be rejected from service.

FAA AD Differences

(f) None.

Other FAA AD Provisions

(g) *Alternative Methods of Compliance (AMOCs):* The Manager, Engine Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

Related Information

(h) Refer to EASA Airworthiness Directive 2007–0136, dated May 14, 2007, for related information.

(i) Contact Christopher Spinney, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e-mail: *christopher.spinney@faa.gov*; telephone (781) 238–7175; fax (781) 238–7199, for more information about this AD.

Material Incorporated by Reference

(j) You must use the service information specified in Table 1 of this AD to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Rolls-Royce plc, P.O. Box 31, DERBY, DE24 8BJ, UK, telephone: 44 (0) 1332 242424; fax: 44 (0) 1332 249936.

(3) You may review copies at the FAA, New England Region, 12 New England Executive Park, Burlington, MA 01803; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

TABLE 1.—MATERIAL INCORPORATED BY REFERENCE

Service Bulletin No.	Page	Revision	Date
RB.211–72–AE753	All	1	May 24, 2005.
RB.211–72–AF197	All	Original	December 20, 2006.

Issued in Burlington, Massachusetts, on October 17, 2007.

Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E7–20913 Filed 10–25–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2006–25671; Airspace Docket No. 07–AWP–3]

Modification of Class D Airspace; Castle Airport, Atwater, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule modifies Class D airspace at Castle Airport, Atwater, CA. This action lowers the ceiling of the Atwater, Castle Class D airspace to below 2.000 feet mean sea level (MSL), changes the southern boundary of the airspace and add an extension to the north. FAA is taking this action to provide controlled airspace for the safety of aircraft executing Standard Instrument Approach Procedures (SIAPs) and other Instrument Flight Rules (IFR) operations at Castle Airport. Except for editorial changes, this rule is the same as the Notice of Proposed Rule Making.

DATES: *Effective Date:* 0901 UTC, February 14, 2008. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Larry Tonish, System Support Specialists, Federal Aviation Administration, Western Service Area, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 917–6766.

SUPPLEMENTARY INFORMATION:

History

On May 29, 2007, the FAA proposed to amend Title 14 Code of the Federal Regulations part 71 (14 CFR part 71) to modify Class D airspace at Castle Airport, Atwater, CA (72 FR 29455). The proposal was the result of an informal meeting on April 26, 2007 with representatives from FAA, local and aviation communities at Atwater, CA. At that meeting, the participants discussed various airspace alternatives designed to accommodate IFR and Visual Flight Rules (VFR) operations in and out of nearby Merced Airport located 6 miles to the south of Castle Airport. The FAA, local and aviation communities agreed on an alternative that would reduce the ceiling of Class D airspace, modify the southern border, and add an extension on the north side of the Class D for safety of aircraft executing SIAP's and other IFR operations at Castle Airport. Class D airspace will be effective during specified dates and times established in advance by a Notice to Airmen. The effective date and time will, thereafter, be published in the Airport/Facility Directory.

Interested parties were invited to participate in this rule making proceeding by submitting written comments on the proposal to the FAA. Eight comments were received, 5 positive and 3 negative. Of the three negative comments, one commenter suggested no change. The no change proposal was discussed at the April 26, 2007 meeting, considered by the FAA and was not adopted because there were no landmarks to identify the common Class D boundary with Merced Airport. The remaining two commenters recommended that the Castle Class D airspace be truncated along Highway 99. This recommendation was also considered by the FAA and not adopted because it would not allow sufficient airspace to conduct terminal operations at Castle Airport.

The Rule

This amendment to 14 CFR part 71 modifies Class D airspace at Castle Airport, Atwater, CA. An Airport Traffic Control Tower (ATCT) is being established at Castle Airport, Atwater, CA, which will meet criteria for Class D airspace. Class D airspace areas are published in Paragraph 5000 of FAA Order 7400.9R, dated August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class D airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. The FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would provide for the safety of aircraft operations at Castle airport.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9R, Airspace Designations and Reporting Points, dated August 15, 2007, and effective

September 15, 2007, is amended as follows:

Paragraph 5000 Class D Airspace area.

* * * * *

AWP CA D Castle Airport, Atwater, CA [Modified]

Castle Airport, Atwater, CA
(Lat. 37°22′50″ N., long. 120°34′05″ W.)

That airspace extending upward from the surface to but not including 2,000 feet MSL beginning at lat. 37°20′22″ N., long. 120°38′49″ W., and extending clockwise around the 4.5-nautical mile radius of the Castle Airport to lat. 37°20′02″ N., long. 120°29′39″ W., thence to the point of beginning; and within 1.9 miles each side of the El Nido VORTAC 320° radial from the 4.5-nautical mile radius to 17.6 miles from the El Nido VORTAC. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Seattle, Washington, on September 10, 2007.

Clark Desing,

Manager, System Support Group, Western Service Center.

[FR Doc. 07–5262 Filed 10–25–07; 8:45 am]

BILLING CODE 4910–13–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1630 and 1631

Technical Amendment to the Flammability Standards for Carpets and Rugs

AGENCY: Consumer Product Safety Commission.

ACTION: Final amendments.

SUMMARY: The Commission is amending the flammability standards for carpets and rugs to remove the reference to Eli Lilly Company Product No. 1588 in Catalog No. 79, December 1, 1969, as the standard ignition source and provide a technical specification defining the ignition source. The specification for the standard ignition source is a timed burning tablet, consisting of essentially pure methenamine, with a nominal heat of combustion value of 7180 calories/gram, a mass of 150 mg +/− 5 mg, flat, and a nominal diameter of 6 mm. The amendment has an immediate effective date.

DATES: The amendment is effective October 26, 2007.

FOR FURTHER INFORMATION CONTACT: Patricia K. Adair, Project Manager, Directorate for Engineering Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–7536.

SUPPLEMENTARY INFORMATION:

A. Background

The standards for surface flammability of carpets and rugs appear at 16 CFR parts 1630 and 1631. They were codified and published in 1975, 40 FR 59931 and 59935 (December 30, 1975). The standards were originally issued in 1970 by the Department of Commerce under the authority of the Flammable Fabrics Act (FFA). Subpart A of 16 CFR parts 1630 and 1631 set forth the standards. Subpart B contains the implementing regulations of the standards. Subpart C contains alternative washing procedures for hide carpets and rugs and wool flotaki carpets and rugs. Subpart D of 16 CFR part 1630 contains the staff interpretations and policies.

16 CFR parts 1630 and 1631 establish minimum acceptance criteria for the surface flammability of carpets and rugs when exposed to a standard small source of ignition, a burning methenamine tablet, under prescribed conditions (the ''pill test''). These standards reduce the risks of death, personal injury, and property damage associated with fires that result from the surface ignition of carpets and rugs.

Both standards require a timed burning tablet as the standard ignition source for flammability performance testing. The standards define the ignition source at 1630.1(f) and 1631.1(f) as a methenamine tablet, weighing approximately 0.149 grams (2.30 grains), sold as Product No. 1588 in Catalog No. 79, December 1, 1969 by the Eli Lilly Company, or an equal tablet.

In April 2002, Commission staff learned that the Eli Lilly Company was no longer producing the methenamine tablets specified in the carpet and rug standards. Although the standards allow for the use of ''an equal'' methenamine tablet and give parameters for chemical composition and weight of the tablet, they do not provide any guidance on determining whether tablets from alternative sources are ''equal'' to those manufactured by the Eli Lilly Company. In July 2003, CPSC staff met with representatives of the Carpet and Rug Institute (CRI) to discuss evaluation of alternative methenamine tablets for use in 16 CFR part 1630 and Part 1631. CRI members were experiencing differing test results using the old Eli Lilly tablets and currently available tablets. CRI members had begun to study the various characteristics of the current tablets. In one case, about 50% of one manufacturer's tablets were found broken in the bottle, with others breaking later. This problem was attributed to the tablets having a domed top. The problem has since been corrected with a flat tablet.

CRI urged the Commission to specify clearly the characteristics of the ''equal'' tablets that should be used for determining compliance to the carpet and rug standards. In an effort to make such a determination, the Commission staff conducted a comparison study to evaluate the weight, chemical composition, and combustion characteristics of presently available brands of methenamine tablets relative to each other and those produced by the Eli Lilly Company. The outcome of the study indicated that tablets consisting of essentially pure methenamine, having a heat of combustion value of approximately 7180 calories/gram and weighing approximately 0.149 grams may be considered equivalent to the tablets produced by the Eli Lilly Company and referenced in the regulation.

On July 29, 2004, the Commission's Office of Compliance issued a letter to industry in response to inquiries received by the CPSC staff regarding the equivalency of methenamine tablets formerly manufactured by the Eli Lilly Company and similar tablets currently produced by other manufacturers. The letter stated that the Commission staff determined that tablets consisting of essentially pure methenamine and weighing approximately 0.149 grams may be considered equivalent to the tablets formerly produced by the Eli Lilly Company. Therefore, tablets meeting these criteria may be used for purposes of determining conformance with the carpet and rug standards.

B. Amending the Flammability Standards

1. Outcome of Commission Testing

As mentioned above, the Eli Lilly Company is no longer producing the methenamine tablets specified in the carpet and rug standards. The standards allow for the use of ''an equal'' methenamine tablet and give parameters for chemical composition and weight of the tablet, but they do not provide any guidance on determining whether tablets from the alternative sources are ''equal'' to those manufactured by the Eli Lilly Company. The Commission staff conducted a comparison study to evaluate the weight, chemical composition, and combustion characteristics of presently available brands of methenamine tablets relative to each other and those produced by the Eli Lilly Company. The outcome of the Commission's comparative study

indicated that tablets consisting of essentially pure methenamine, having a heat of combustion value of approximately 7,180 calories/gram and weighing approximately 0.149 grams may be considered equivalent to the tablets produced by the Eli Lilly Company and referenced in the regulation.

2. Proposed Amendment

On November 13, 2006, the Commission issued a **Federal Register** notice to amend the flammability standards for carpets and rugs to remove the reference to the Eli Lilly Company's tablet as the standard ignition source and provide a generic specification defining the ignition source at § 1630.1(f) and § 1631.1(f) and solicited public comments. The Commission received one comment in support of the proposal, and one objecting to flammability testing as a mandatory requirement and recommending that compliance with the standards be voluntary to avoid potential trade restrictions on woolen rugs.

On January 12, 2007, the Commission issued a **Federal Register** notice providing interested persons the opportunity for oral or written presentations regarding the proposed technical amendment to the flammability standards for carpets and rugs. No responses to the **Federal Register** notice were received.

3. Final Rule

The carpet and rug flammability standards were issued under section 4 of the FFA (15 U.S.C. 1193), which authorizes the issuance or amendment of flammability standards to protect the public against unreasonable risks of fire leading to death, personal injury, or significant property damage. As required by section 4(b) of the FFA, both standards are based on findings that they are needed to adequately protect the public against the unreasonable risk of the occurrence of fire leading to death, personal injury, or significant property damage.

Section 4(j)(1) of the Flammable Fabrics Act requires the Commission to prepare a final regulatory analysis before issuing a final rule. The regulatory analysis must contain a description of the potential benefits and costs of the regulation, a description of any alternatives to the final regulation, and a summary of any significant issues raised by the comments submitted during the public comment period. The Commission must also find that the benefits expected from the rule bear a reasonable relationship to its costs and that the rule imposes the least burdensome requirement which prevents or adequately reduces the risk of injury for which the regulation is being promulgated. 15 U.S.C. 1193(j)(2).

Potential Costs and Benefits

Since 2002, when production of the previous methenamine tablet was discontinued by its manufacturer, producers and importers of carpets and rugs that comply with the standards have been performing tests with ''equivalent'' methenamine tablets. The technical amendment will, therefore, maintain current industry practice. The technical amendment to redefine the methenamine tablet will have no significant impact on expected benefits or costs of the flammability standards for carpets and rugs.

4. Comments

The Commission received two comments on the proposed rule. The American Fiber Manufacturers Associated supported the technical amendment as proposed. The Permanent Mission of India to the World Trade Organization objected to flammability as a mandatory requirement and recommended that compliance with the standards be voluntary to avoid potential trade restrictions on woolen rugs. The Commission notes that the standards have been in effect since 1970; the amendment only provides a generic specification for the ignition source and will not alter the overall scope of the standards. Thus, the amendment will have no impact on U.S. or international trade.

Review of Other Existing Standards

The Commission staff is aware of one U.S. voluntary standard regarding the type of ignition source to be used in testing the flammability of carpets and rugs. This standard, ASTM D2859–04, ''Standard Test Method for Ignition Characteristics of Finished Textile Floor Covering Materials,'' describes the use of the Eli Lilly Tablet as satisfactory. It also states that ''normal variation in the weight of the different tablets will not affect the test results.''

There is an existing international voluntary standard developed by the International Organization for Standardization in 1982 (ISO 6925), that describes a tablet test for the flammability of textile floor coverings. The prescribed tablets are of ''hexamethylenetetramine, flat, having a mass of 150mg (plus or minus 5mg) and a diameter of 6mm.'' The allowable variance is about 3.3%. The mass expressed in ISO 6925 is essentially equivalent to that specified in the U.S. Standards under the FFA. While the ISO standard did not identify the Eli Lilly tablet, it noted that the tablets were commercially available. Thus, the ISO-specified tablet is equivalent to the Eli Lilly tablet in its specifications.

Canada's 1973 mandatory standard for carpets and textile floor coverings under the Hazardous Products Act, CGSB 4–GP–2, also specifies in its appendix the Eli Lilly tablet as the ignition source. It notes that ''normal variation in weight * * * will not affect the test results.''

5. Effective Date

Section 4(b) of the FFA (15 U.S.C. 1193(b)) provides that an amendment of a flammability standard shall become effective one year from the date it is promulgated, unless the Commission finds for good cause that an earlier or later effective date is in the public interest, and publishes that finding. Because manufacturers are already using ''equal'' methenamine tablets as allowed by the current standards, the Commission finds that an immediate effective date upon publication of the amendments is appropriate.

C. Other Issues

1. Impact on Small Businesses

In accordance with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), in the proposed rule, the Commission preliminarily certified that these amendments to the carpet and rug flammability standards would not have a significant economic impact on a substantial number of small entities, including small businesses. 71 FR 66,145. No information available to the Commission since the issuance of the proposed rule warrants changing this preliminary certification. The amendments keep current industry practices and procedures in place. No additional actions will be required of small entities. Based on available information, there will be little or no effect on small producers of carpets and rugs, since the standards already require that all carpets and rugs meet the criteria of the tests, and, given the equivalence of the test tablets, the results of the tests should be the same. Accordingly, the Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

2. Environmental Considerations

The amendments fall within the categories of Commission actions described at 16 CFR 1021.5(c) that have little or no potential for affecting the human environment. The amendments are not expected to have a significant

effect on production processes or on the types or amounts of materials used for the manufacture of carpets and rugs. The amendments will not render existing inventories unsalable, or require destruction of existing goods. The Commission has no information indicating any special circumstances in which these amendments may affect the human environment. For that reason, as discussed in the proposed rule, neither an environmental assessment nor an environmental impact statement is required. 71 FR 66145.

3. Executive Order 12988

Executive Order 12988, Civil Justice Reform, (February 5, 1996), requires that the Commission specify the preemptive effect, if any, to be given each new regulation. This technical amendment does not alter the preemptive effect of the underlying regulation.

List of Subjects in 16 CFR Parts 1630 and 1631

Carpets, Consumer protection, Flammable materials, Floor coverings, Labeling, Records, Rugs, Textiles, Warranties.

Conclusion

■ Therefore, pursuant to the authority of section 30(b) of the Consumer Product Safety Act (15 U.S.C. 2079(b)) and sections 4 and 5 of the Flammable Fabrics Act (15 U.S.C. 1193, 1194), the Commission hereby amends title 16 of the Code of Federal Regulations, Chapter II, Subchapter D, parts 1630 and 1631 to read as follows:

PART 1630—STANDARD FOR THE SURFACE FLAMMABILITY OF CARPETS AND RUGS

■ 1. The authority for subpart A of part 1630 continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–570; 15 U.S.C. 1193.

■ 2. Section 1630.1(f) is revised to read as follows:

§ 1630.1 Definitions.

* * * * *

(f) *Timed Burning Tablet* (pill) means a methenamine tablet, flat, with a nominal heat of combustion value of 7180 calories/gram, a mass of 150 mg +/ −5mg and a nominal diameter of 6mm.

* * * * *

■ 3. Section 1630.4 is amended by revising the first sentence of paragraph (a) (3) to read as follows:

§ 1630.4 Test procedure.

(a) * * *

(3) *Standard igniting source.* A methenamine tablet, flat, with a nominal heat of combustion value of 7180 calories/gram, a mass of 150 mg +/ −5 mg and a nominal diameter of 6mm.

* * *

PART 1631—STANDARD FOR THE SURFACE FLAMMABILITY OF SMALL CARPETS AND RUGS

■ 1. The authority for subpart A of part 1631 continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–570; 15 U.S.C. 1193.

■ 2. Section 1631.1(f) is revised to read as follows:

§ 1631.1 Definitions.

* * * * *

(f) *Timed Burning Tablet* (pill) means a methenamine tablet, flat, with a nominal heat of combustion value of 7180 calories/gram, a mass of 150 mg +/ −5mg and a nominal diameter of 6mm.

* * * * *

■ 3. Section 1631.4 is amended by revising the first sentence of paragraph (a)(3) to read as follows:

§ 1631.4 Test procedure.

(a) * * *

(3) *Standard igniting source.* A methenamine tablet, flat, with a nominal heat of combustion value of 7180 calories/gram, a mass of 150 mg +/ −5 mg and a nominal diameter of 6mm.

* * *

Dated: October 16, 2007.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. ''Briefing Package: Technical Amendment to the Flammability Standards for Carpets and Rugs, 16 CFR part 1630 and 16 CFR part 1631,'' U.S. Consumer Product Safety Commission, October 3, 2006.

2. Technical Amendment to the Flammability Standards for Carpets and Rugs; Proposed Amendments, 71 FR 66145 (November 13, 2006).

3. Proposed Technical Amendment to the Flammability Standards for Carpets and Rugs; Notice of Opportunity for Oral Comment, 72 FR 1472 (January 12, 2007).

[FR Doc. E7–20666 Filed 10–25–07; 8:45 am]

BILLING CODE 6355–01–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 18

RIN 3038–AC22

Maintenance of Books, Records and Reports by Traders

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (Commission) is amending Commission Regulation 18.05 in two respects: to make it explicit that persons holding or controlling reportable positions on a designated contract market (DCM) or derivatives transaction execution facility (DTEF) must retain books and records and make available to the Commission upon request any pertinent information with respect to all other positions and transactions in the commodity in which the trader has a reportable position, including positions held or controlled or transactions executed on all reporting markets, over-the-counter (OTC) and/or pursuant to Sections 2(d), 2(g) or 2(h)(1)–(2) of the Commodity Exchange Act (Act) or Part 35 of the Commission's regulations, on exempt commercial markets operating pursuant to Sections 2(h)(3)–(5) of the Act (ECMs), on exempt boards of trade operating pursuant to Section 5d of the Act (EBOTs), and on foreign boards of trade (FBOTs); and to make the regulation clearer and more complete with respect to hedging activity. The amendments will enhance the Commission's ability to deter and prevent price manipulation or any other disruptions to the integrity of the regulated futures markets, help to ensure the avoidance of systemic risk, and clarify the meaning of the regulation.

DATES: *Effective Date:* November 26, 2007.

FOR FURTHER INFORMATION CONTACT: Duane C. Andresen, Special Counsel, Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone 202–418–5492; e-mail *dandresen@cftc.gov*.

SUPPLEMENTARY INFORMATION:

I. Purpose of Regulation 18.05 and Statutory Basis

Section 3(b) of the Act [1] declares that the purpose of the Act is to, among

[1] 7 U.S.C. § 5(b) (2007). § 3(b) of the Act provides in full:

It is the purpose of this chapter to serve the public interests described in subsection (a) of this section through a system of effective self-regulation of trading facilities, clearing systems, market participants and market professionals under the oversight of the Commission. To foster these public interests, it is further the purpose of this chapter to deter and prevent price manipulation or any other disruptions to market integrity; to ensure the financial integrity of all transactions subject to this chapter and the avoidance of systemic risk; to protect all market participants from fraudulent or other abusive sales practices and misuses of

Continued

other things, deter and prevent price manipulation or any other disruptions to market integrity and to ensure the financial integrity of all transactions subject to the Act and the avoidance of systemic risk. Section 4i of the Act [2] requires persons holding futures or option positions at DCMs or DTEFs at or above certain levels to keep books and records of all:

(1) Transactions and positions in the exchange-traded commodity;

(2) Transactions and positions in any such commodity traded on or subject to the rules of any other board of trade; and

(3) Cash or spot transactions in, and inventories and purchase and sale commitments of such commodity.

Such books and records must be open at all times for inspection by any representative of the Commission or the Department of Justice.

Section 8a(5) of the Act [3] provides explicit authority to the Commission to make and promulgate such rules and regulations as, in the judgment of the Commission, are reasonably necessary to effectuate any of the provisions or to accomplish any of the purposes of the Act. In order to accomplish the purposes of Sections 3(b) and 4i set forth above, the Commission has promulgated regulations creating market and large trader reporting requirements.[4] Included among these regulations is a requirement that persons holding futures or option positions at DCMs or DTEFs (reporting markets) [5] at or above reportable levels (reportable positions) [6] be identified to the Commission through the large trader reporting system (LTRS).

The LTRS, which requires that clearing members, futures commission merchants (FCM) and foreign brokers file daily reports with the Commission, enables the Commission to assess an individual trader's activities and potential market power and to enforce the Commission or DCM-set limits on speculative positions.[7] Once a trader holds a reportable position, the trader is subject to Commission Regulation 18.05,[8] which requires that the trader keep books and records showing all details concerning:

(1) All positions and transactions for future delivery in the commodity on all reporting markets;

(2) All positions and transactions in the commodity option;

(3) All positions and transactions in the cash commodity, its products and byproducts; and

(4) Commercial activities that the trader hedges in the commodity underlying the futures contract in which the trader is reportable.[9]

A reportable trader is required to furnish to the Commission, upon request, any pertinent information concerning these positions, transactions or activities. [10] Traders who do not hold reportable positions do not have obligations under Regulation 18.05.

II. Proposal

A. Introduction

In order to enhance its ability to detect and prevent manipulation of regulated markets and products and to ensure the avoidance of systemic risk, as well as to clarify the meaning of the regulation and bring it up to date, the Commission published in the **Federal Register** a proposal to amend Regulation 18.05 in the following respects: [11]

1. To make it explicit that persons holding or controlling reportable positions on a reporting market must retain books and records and make available to the Commission upon request pertinent information with respect to all non-reporting transactions, *i.e.*, all positions and transactions in the commodity in which the trader is reportable, including transactions

customer assets; and to promote responsible innovation and fair competition among boards of trade, other markets and market participants.

[2] 7 U.S.C.§ 6i (2007). § 4i of the Act provides:

It shall be unlawful for any person to make any contract for the purchase or sale of any commodity for future delivery on or subject to the rules of any contract market or derivatives transaction execution facility—

(1) if such person shall directly or indirectly make such contracts with respect to any commodity or any future of such commodity during any one day in an amount equal to or in excess of such amount as shall be fixed from time to time by the Commission, and

(2) if such person shall directly or indirectly have or obtain a long or short position in any commodity or any future of such commodity equal to or in excess of such amount as shall be fixed from time to time by the Commission, unless such person files or causes to be filed with the properly designated officer of the Commission such reports regarding any transactions or positions described in clauses (1) and (2) hereof as the Commission may by rule or regulation require and unless, in accordance with rules and regulations of the Commission, such person shall keep books and records of all such transactions and positions and transactions and positions in any such commodity traded on or subject to the rules of any other board of trade, and of cash or spot transactions in, and inventories and purchase and sale commitments of such commodity. Such books and records shall show complete details concerning all such transactions, positions, inventories, and commitments, including the names and addresses of all persons having any interest therein, and shall be open at all times to inspection by any representative of the Commission or the Department of Justice. For the purposes of this section, the futures and cash or spot transactions and positions of any person shall include such transactions and positions of any persons directly or indirectly controlled by such person.

[3] 7 U.S.C. 12a(5) (2007).

[4] The Commission's market and large trader reporting rules are contained in Parts 15 through 21 of the Commission's regulations.

[5] Pursuant to Commission Regulation 15.00(m), a reporting market means a DCM and, unless determined otherwise by the Commission with respect to the facility or a specific contract listed by the facility, a DTEF.

[6] Pursuant to Commission Regulation 15.00(l), reportable position means:

(1) For reports specified in parts 17, 18 and § 19.00(a)(2) and (a)(3) of this chapter any open contract position that at the close of the market on any business day equals or exceeds the quantity specified in § 15.03 of this part in either:

(i) Any one future of any commodity on any one reporting market, excluding future contracts against which notices of delivery have been stopped by a trader or issued by the clearing organization of a reporting market; or

(ii) Long or short put or call options that exercise into the same future of any commodity, or long or short put or call options for options on physicals that have identical expirations and exercise into the same physical, on any one reporting market.

(2) For the purposes of reports specified in § 19.00(a)(1) of this chapter, any combined futures and futures-equivalent option open contract position as defined in part 150 of this chapter in any one month or in all months combined, either net long or net short in any commodity on any one reporting market, excluding futures positions against which notices of delivery have been stopped by a trader or issued by the clearing organization of a reporting market, which at the close of the market on the last business day of the week exceeds the net quantity limit in spot, single or in all-months fixed in § 150.2 of this chapter for the particular commodity and reporting market.

[7] The Commission also uses large trader reporting information as a means to ensure the avoidance of systemic risk in that such information enables Commission staff to determine which FCMs carrying accounts might have exposure in particular markets.

[8] Regulation 18.05 states in full:

Every trader who holds or controls a reportable futures or option position shall keep books and records showing all details concerning all positions and transactions for future delivery in the commodity on all reporting markets, all positions and transactions in the commodity option, and all positions and transactions in the cash commodity, its products and byproducts and, in addition, commercial activities that the trader hedges in the commodity underlying the futures contract in which the trader is reportable, and shall upon request furnish to the Commission any pertinent information concerning such positions, transactions or activities.

[9] In describing the requirements of Regulation 18.05 in 1981, the Commission stated:

The regulation requires reportable traders to maintain books and records of futures positions and transactions in the commodity in which they are reportable and all positions and transactions in the cash commodity and its products and byproducts * * *. [T]he Commission wishes to underscore its view that the book and recordkeeping requirements and inspection provision contained therein are essential to accomplish the purposes of the Act and within the Commission's authority to adopt pursuant to section[s] 4i and 8a(5) of the Act. These requirements have always applied to the traders who hold or control a reportable position, and have not been restricted in any way. ''Reporting Requirements for Contract Markets, Futures Commission Merchants, Members of Exchanges and Large Traders,'' 46 FR 59960, 59963 (December 8, 1981) (footnote omitted).

[10] The Commission currently requests such information an average of three times per year.

[11] 72 FR 34413 (June 22, 2007).

executed on all reporting markets, OTC and/or pursuant to Sections 2(d), 2(g) or 2(h)(1)–(2) of the Act or Part 35 of the Commission's regulations, on ECMs operating pursuant to Sections 2(h)(3)–(5) of the Act, on EBOTs operating pursuant to Section 5d of the Act, and on FBOTs; and

2. To make the regulation clearer and more complete with respect to hedging activity.

B. Proposed Amendments Related to Recordkeeping and Reporting

The proposal recognized that there is a close relationship among transactions conducted on reporting markets and non-reporting transactions and that it is sometimes necessary to determine all transactions and positions in the commodity in which the trader is reportable in order to more effectively detect and prevent manipulation of regulated markets and products and to ensure the avoidance of systemic risk.[12] The Commission recognized that it is particularly important that staff be able to assess the reportable trader's overall position in the same commodity in light of the growing volume of trading on the non-reporting markets, the close relationship among the various products and markets, the increasing globalization of the futures markets, and the growth of trading on FBOTs.[13]

The proposal noted that while Regulation 18.05 explicitly requires that a trader holding reportable positions keep books and records and provide to the Commission, upon request, pertinent information with respect to positions and transactions in the underlying commodity on DCMs and DTEFs, it does not explicitly do so with respect to positions and transactions in virtually identical contracts executed on ECMs, EBOTs or FBOTs or in the same commodity executed OTC and/or pursuant to Sections 2(d), 2(g) or 2(h)(1)–(2) of the Act or Part 35 of the Commission's regulations. The Commission noted that information concerning non-reporting transactions is important to its ability to conduct effective market surveillance of the DCM and DTEF contracts. Thus, if a trader is reportable because of futures or option positions in a contract on a DCM or DTEF, the trader's books and records with respect to non-reporting positions and transactions in the same commodity are relevant to effective surveillance and supervision of the DCM or DTEF contract in which the trader is reportable.

The proposal noted that the Act provides ample authority to require keeping books and records and providing pertinent information concerning non-reporting transactions. Section 4i explicitly encompasses non-reporting transactions on ''any other board of trade'' (such as FBOTs, ECMs operating pursuant to Sections 2(h)(3)–(5) of the Act, and EBOTs operating pursuant to Section 5d of the Act) and in the form of cash or spot transactions, inventories, and purchase and sale commitments. Further, Section 3(b) of the Act declares that the purpose of the Act is to, among other things, deter and prevent price manipulation or any other disruptions to market integrity and to ensure the avoidance of systemic risk. Section 8a(5) of the Act authorizes the Commission to promulgate such regulations as, in its judgment, are reasonably necessary to accomplish any of the purposes of the Act. As noted in the proposal, amending Regulation 18.05 to clearly require that reportable traders keep books and records showing all details concerning non-reporting transactions in the reportable commodity is a reasonably necessary means of accomplishing the purposes of Section 3(b) of the Act.

The proposal also noted that although non-reporting transactions themselves generally are not subject to most regulatory provisions of the Act, the futures or option transactions executed and maintained on a DCM or DTEF that result in a reportable position are subject to such provisions and, pursuant to Section 3(a) of the Act, are affected with a national public interest. It is the purpose of the Act pursuant to Section 3(b) that the Commission deter and prevent price manipulation of all commodities traded on these regulated markets. The proposal stated that to accomplish this purpose, it is necessary that the Commission have the ability to review all activities in commodities traded on these markets, regardless of where the transactions are executed. By taking a position on a regulated market, a trader agrees to abide by the rules of the market and the Commission, including prohibitions against manipulation. To enhance its ability to detect and deter manipulation and other threats to market integrity, the Commission requires persons holding reportable positions to maintain books and records of transactions that could impact the regulated market and related cash market, including non-reporting transactions.

Finally, the proposal noted that staff has interpreted Regulation 18.05 to include position and transaction data for non-reporting transactions and has received such information in response to requests made pursuant to the Regulation. Thus, consistent with the Act and Commission practice, the Commission proposed to amend Regulation 18.05 to make explicit that a trader with a reportable position must keep books and records showing all details concerning all non-reporting transactions in the same commodity and provide pertinent information to the Commission upon request.

C. Amendments Related to Clarity and Completeness

The proposal also noted that there are two issues that arise in connection with the Regulation 18.05 requirement that traders keep books and records showing all details concerning ''commercial activities that the trader hedges in the commodity underlying the futures contract in which the trader is reportable.'' First, the phrase has led to some confusion. Originally inserted into the paragraph as ''commercial activities that the trader hedges in the futures commodity in which the trader is reportable,'' its purpose was to require that, ''in addition to books and records of positions or transactions in a cash commodity, a reportable trader must also maintain records of commercial activities which the trader hedges.'' [14] Second, the proposal stated that reportable positions can be option positions, as well as futures positions, but it is not clear that the current language also addresses commercial activities that the trader hedges in the commodity underlying any option contract in which the trader is reportable.

The Commission therefore proposed to amend the regulation to revert to the original approach and include hedges in the option contract in which the trader is reportable. By modifying the phrase to read ''commercial activities that the trader hedges in the futures or option contract in which the trader is reportable,'' Regulation 18.05 captures information with respect to hedges in other than the cash commodity, its products or byproducts (i.e., a trader with a reportable position in gold futures or options that is a hedge of a cash position in silver would be required to comply with the Regulation 18.05 requirements with respect to the silver position).

[12] *See* sections 6(c), 6c, 6(d) and 9(a)(2) of the Act for the Commission's antimanipulation authority.

[13] For instance, since 1999, Commission staff, through foreign terminal no-action letters, has allowed 19 FBOTs to make their trading systems available by direct access to members and other participants in the U.S. without requiring the FBOTs to register as DCMs or DTEFs.

[14] 46 FR 42463, 42466 (August 21, 1981).

III. Comments Regarding the Proposal

The Commission received six comment letters on its proposal. Commenters included the American Public Gas Association (APGA), the Industrial Energy Consumers of America (IECA), the International Swaps and Derivatives Association, Inc. (ISDA), the Managed Funds Association (MFA), the New York Public Service Commission (NYPSC), and the New York Mercantile Exchange (NYMEX). Most of the commenters generally endorsed the proposal and/or its underlying purpose, but felt that additional steps are necessary to resolve the underlying matters that the proposal is intended to address. Two commenters raised concerns regarding the recordkeeping and reporting aspects of the proposal.

The APGA commented that it strongly supports the proposed amendment but is concerned about the economic links between NYMEX and OTC contracts and believes that further steps are necessary for the Commission to carry out surveillance of the natural gas markets. It expressed concern that the LTRS does not routinely reach traders' large OTC positions and noted that it has petitioned Congress to provide the Commission with authority for a LTRS with respect to trading in financial contracts in natural gas. Further, the APGA commented that reliance on special call authority leaves open the potential for manipulation or other disruptive behavior with little risk of detection until after damage to the market has been done.

The IECA commented that it supports the proposal but noted that requiring companies to keep books and records does not prevent market manipulation and that preemptive monitoring of entities with large positions that cover both futures and OTC markets is necessary. Further, such entities should be required to report daily to the Commission. The IECA also recommended that the Commission support the establishment of an advisory panel on energy markets with consumer participation thereon.

The NYPSC noted that it supports the proposed rule and its underlying purpose and that given the increases in natural gas prices over the past several years, the relevant government entities must take all available steps to prevent market manipulation and ensure the integrity of the natural gas markets. The NYPSC maintained that it is essential to evaluate exposure on both NYMEX and the InterContinental Exchange (ICE), an ECM, and stated that the Commission's inability to directly regulate traders that use ICE exclusively creates a serious loophole in effective regulatory oversight of the financial markets. Concerned that traders will avoid regulatory oversight by trading exclusively on ICE, the NYPSC recommended that the Commission should monitor the migration of traders that currently utilize NYMEX to ICE as the exclusive means of trading natural gas contracts.

The ISDA and the MFA voiced support for the proposal but raised concerns about the proposal's recordkeeping and reporting obligations. The ISDA stated its view that the proposal does not create additional recordkeeping or reporting obligations and requested clarification with respect to the scope of Regulation 1.35(a), which contains recordkeeping and reporting language similar to that in proposed Regulation 18.05. Further, the ISDA requested clarification that the records required to be retained under proposed Regulation 18.05 are subject to Regulation 1.31 retention requirements and consist of accurate records of positions and actual transaction documentation created in the ordinary course of business. The MFA requested that the Commission confirm that the current system of books and records maintained by traders in the normal course of business and in the format created in the normal course of business would meet the proposal's recordkeeping and retention requirements.

The NYMEX voiced support for the intention underlying the proposal but commented that the purpose of the proposal can be met only by imposing identical requirements on linked trading facilities meeting specified criteria. NYMEX posited that the proposal, if implemented, would create an incentive for market participants to do all their trading at unregulated or non-transparent venues or to trade at a level below the reportable level on the regulated exchange. Further, NYMEX commented that the proposal was limited in effectiveness because of the anticipated infrequent use of the special call procedure; would impose a cost on the regulated exchanges because of the shift in trading activity; and would have adverse public policy consequences. NYMEX recommended that the Commission defer the amendments to Regulation 18.05 in favor of a more comprehensive legislative approach that would result in the implementation of reporting requirements on organized trading facilities that have triggered specified criteria.[15]

The Commission has carefully considered the comments submitted and has decided, for reasons cited herein and in the proposal, to amend the regulation as proposed. As previously stated, staff has interpreted Regulation 18.05 to include position and transaction data for non-reporting transactions and has received such information in response to requests made pursuant to the Regulation. Thus, the proposal to amend Regulation 18.05 merely makes explicit what has been implicit.

NYMEX's comment that the proposal would lead market participants to move their trading activity to unregulated or non-transparent venues, or trade at a level below the reportable level on the regulated exchange in order to avoid the consequences of holding reportable positions, is highly speculative and, in the Commission's estimation, unlikely. As previously discussed, the amendments to Regulation 18.05 clarify existing authority and, accordingly, any ''disincentive'' for traders to trade on a regulated market already exists, with or without the amendments. In addition, the Commission sees little merit in following NYMEX's suggestion to defer in favor of a legislative approach. The Commission can control neither the timing nor the terms of legislation addressing reporting obligations on currently non-reporting markets, or even whether such legislation is enacted in the first instance. Should legislation in this area be enacted which expands the Commission's jurisdiction with respect to transactions that are currently non-reportable, further amendments to the regulation could be considered.

With respect to the comments regarding the proposal's recordkeeping and reporting obligations, the Commission confirms that the amendments should not change current recordkeeping or reporting obligations, assuming that traders are currently keeping complete transaction records. Records required to be retained under Regulation 18.05 consist of accurate records of positions and actual transaction documentation created in the ordinary course of business. Thus, books and records that currently should be maintained by traders in the normal course of business and in the format created in the normal course of business would meet the regulation's recordkeeping requirements. Such records are subject to the Regulation 1.31 retention requirements. Finally,

[15] As noted above, other commenters also recommended legislation action, i.e., to provide the Commission with authority for a LTRS with respect to trading in financial contracts in natural gas on non-reporting markets and to require entities that control large positions in the OTC market to report daily to the Commission.

Regulation 18.05 does not alter or add to the Regulation 1.35(a) recordkeeping and reporting requirements.

IV. Related Matters

A. Cost Benefit Analysis

Section 15(a) of the Act requires the Commission to consider the costs and benefits of its action before issuing a new regulation or order under the Act. By its terms, Section 15(a) does not require the Commission to quantify the costs and benefits of a new regulation or to determine whether the benefits of the regulation outweigh its costs. Rather, Section 15(a) simply requires the Commission to ''consider the costs and benefits'' of its action.

Section 15(a) further specifies that the costs and benefits of the rule or order shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission may, in its discretion, give greater weight to any one of the five enumerated areas of concern and may, in its discretion, determine that, notwithstanding its costs, a particular rule or order is necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the Act.

The Commission's proposal contained an analysis of its consideration of these costs and benefits and solicited public comment thereon. As previously noted, NYMEX commented that the proposal, by adding another incentive for market participants to shift their trading activity from regulated and transparent venues to unregulated and non-transparent venues, would impose a cost on the regulated exchanges and would have adverse public policy consequences. NYMEX also questioned the extent of the benefits to be obtained from the proposal in light of the acknowledgement that special calls for information would continue to be made on an infrequent basis.

The Commission believes, as it stated in the discussion of NYMEX's comments above, that attempting to discern what impact amended Regulation 18.05 will have on potential large traders, or what costs to the regulated exchanges would be associated with any shift in trading activity, is highly speculative. Because the amendments clarify existing authority, any ''disincentive'' for traders to trade on a regulated market already exists, with or without the amendments. Additionally, the Commission finds no merit in the contention that the extent of the benefits to be obtained from the amendments are questionable in light of the acknowledgement that special calls for information would continue to be made on an infrequent basis. The Commission is confident that such special calls will be made when deemed necessary and that the information provided in response to such special calls will assist the Commission in meeting its regulatory responsibilities.

After consideration of the costs and benefits and the public comments received thereon, the Commission has determined to adopt the amendments to Regulation 18.05 set forth below.

B. The Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires that agencies consider the impact of their rules on small businesses. The Commission has previously determined that exchanges, futures commission merchants and large traders are not ''small entities'' for the purposes of the RFA.[16] The requirements related to the amended recordkeeping and reporting rule fall on large traders. Accordingly, the Acting Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the actions adopted herein will not have a significant economic impact on a substantial number of small entities.

C. The Paperwork Reduction Act

The Paperwork Reduction Act (PRA)[17] imposes certain requirements on Federal agencies, including the Commission, in connection with conducting or sponsoring any collection of information as defined by the PRA. 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. In its proposal, the Commission noted that the proposed amendments would require traders with reportable positions to keep books and records showing all details concerning all positions and transactions in the commodity in which the trader is reportable and to furnish to the Commission, upon request, any pertinent information concerning such positions, transactions or activities in a form acceptable to the Commission and that this information is part of an approved collection of information. The Commission further noted that the proposed amendments would not result in any material modifications to this approved collection. Accordingly, for purposes of the PRA, the Commission certified that the proposed amendment did not impose any new reporting or recordkeeping requirements.

The Commission submitted the proposed rule amendments and their associated information collection requirements to the Office of Management and Budget (OMB) for its review. No comments were received in response to the Commission's invitation in the notice of proposed rulemaking to comment on the information which would be required by the proposed rule amendments.

[16] 47 FR 18618, 18618–21 (April 30, 1982).

[17] Public Law 104–13 (May 13, 1995).

List of Subjects in 17 CFR Part 18

Commodity futures, Reporting and recordkeeping requirements.

■ Accordingly, 17 CFR Chapter I is amended as follows:

PART 18—REPORTS BY TRADERS

■ 1. The authority citation for part 18 is revised to read as follows:

Authority: 7 U.S.C. 2, 4, 5, 6a, 6c, 6f, 6g, 6i, 6k, 6m, 6n, 12a and 19; 5 U.S.C. 552 and 552(b), unless otherwise noted.

■ 2. Revise § 18.05 to read as follows:

§ 18.05 Maintenance of books and records.

(a) Every trader who holds or controls a reportable futures or option position shall keep books and records showing all details concerning all positions and transactions in the commodity:

(1) On all reporting markets;

(2) Over the counter and/or pursuant to Sections 2(d), 2(g) or 2(h)(1)–(2) of the Act or Part 35 of this chapter;

(3) On exempt commercial markets operating pursuant to Sections 2(h)(3)–(5) of the Act;

(4) On exempt boards of trade operating pursuant to Section 5d of the Act; and

(5) On foreign boards of trade.

(b) Every such trader shall also keep books and records showing all details concerning all positions and transactions in the cash commodity, its products and byproducts, and all commercial activities that the trader hedges in the futures or option contract in which the trader is reportable.

(c) The trader shall upon request furnish to the Commission any pertinent information concerning such positions, transactions, or activities in a form acceptable to the Commission.

Issued in Washington, DC, this 22nd day of October, 2007, by the Commission.

David A. Stawick,

Secretary of the Commission.

[FR Doc. E7–21077 Filed 10–25–07; 8:45 am]

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DEPARTMENT OF THE TREASURY

Monetary Offices

31 CFR Part 92

RIN 1506–AA58

Assessment of Civil Penalties for Misuse of Words, Letters, Symbols, and Emblems of the United States Mint

AGENCY: United States Mint, Treasury.

ACTION: Final rule.

SUMMARY: The United States Mint is adopting a new rule establishing procedures under which the United States Mint will implement and execute the provisions of 31 U.S.C. 333(c), which authorizes the Secretary of the Treasury to assess a civil penalty against any person who has misused the words, titles, abbreviations, initials, symbols, emblems, seals, or badges of the United States Mint.

DATES: *Effective Date:* This final rule is effective November 26, 2007.

FOR FURTHER INFORMATION CONTACT: James Adler, Senior Attorney, United States Mint, at (202) 354–7286.

SUPPLEMENTARY INFORMATION: The United States Mint is adopting today the new regulation set forth below under 31 CFR part 92.

I. Background

Section 333(c) of title 31, United States Code, authorizes the Secretary of the Treasury to assess a civil penalty against any person who has misused the words, titles, abbreviations, initials, symbols, emblems, seals, or badges of the Department of the Treasury, including those of the United States Mint. The Secretary of the Treasury has delegated to the Director of the United States Mint the authority to enforce the civil penalty provisions of 31 U.S.C. 333(c) with respect to the misuse of United States Mint words, titles, abbreviations, initials, symbols, seals, trademarks, and badges, and with respect to the misuse of Department of the Treasury words, titles, abbreviations, initials, symbols, seals, trademarks, and badges when in connection with activities related to United States Mint operations and programs. This rule establishes procedures that the United States Mint will follow to carry out that authority and to ensure that those assessed a civil penalty under 31 U.S.C. 333(c) are accorded due process. These procedures are based on the procedures of the Department of the Treasury at 31 CFR part 27.

II. Notice of Proposed Rulemaking

This final rule is based on the notice of proposed rulemaking published Wednesday, January 12, 2005 (the ''NPRM'') (70 FR 2081). The NPRM sought public comment on the proposed rule.

The comment period for the NPRM ended on February 18, 2005. The United States Mint received 17 comments from members of the public, businesses and trade associations. The Federal Trade Commission also submitted a staff comment.

III. Summary of Comments

Eight of the comments were from members of the public. Seven of the eight expressed support for the United States Mint's proposed regulation. One of these comments objected to the use of names by companies that ''attempt to confuse the public into the belief that the product is being sold and promoted by the U.S. Mint.'' Another expressed the opinion, ''You should come down as hard as possible on these companies.'' A third stated, ''I strongly recommend the proposal maintained be adopted that would prevent firms from cashing in on U.S. Mint.'' A fourth asserted that it is ''about time the U.S. Mint played hardball and protected its products. Use of Mint products to make money by misleading new collectors gives a black eye to collecting.'' The eighth submission enclosed a newspaper article on the proposed regulation without comment.

A. Discussion of Substantive Comments From the Public

Substantive comments from the public included a request that the United States Mint not ''limit penalties to audience size'' and a suggestion that ''civil penalties must include a clause for full restitution for those customers who purchased the items that were marketed in violation of the statute.''

As to the comment on restitution, we note that the proposed regulation would have permitted the imposition of a ''civil monetary penalty and/or civil or equitable remedy.'' Upon further examination of 31 U.S.C. 333(c) and the statute's legislative history, however, we have determined that the term ''civil penalty'' in this regulation should refer only to a monetary penalty payable to the Treasury. Accordingly, the final regulation will permit an assessing official to impose a civil monetary penalty on a person ''who violates the provisions of paragraph (a) of this section.'' The phrase ''civil penalty'' is defined in the regulation to mean ''(1) A civil monetary penalty.'' Consistent with our view of the underlying statutory authority, therefore, the final regulation will not permit the United States Mint to order restitution as a remedy. This, of course, is in no way intended to limit any relief to which a person who is injured by the misleading use of United States Mint names or symbols may be entitled in private litigation or through an enforcement action by another Federal or state agency.

With regard to the comment that the United States Mint not ''limit penalties to audience size,'' the proposed regulation's operative clause with regard to the amount of penalty imposed for a violation reads as follows:

> (c) *Civil penalty.* The assessing official may impose a civil penalty on any person who violates the provisions of paragraph (a) of this section. The amount of a civil penalty shall not exceed $5,000 for each and every use of any material in violation of paragraph (a) of this section, except that such penalty shall not exceed $25,000 for each and every use if such use is in a broadcast or telecast.

These provisions do not limit penalties to ''audience size,'' but are based on each misuse of material and may be as high as $25,000 for each and every misuse if the misuse is in a broadcast or telecast.

In reviewing the public comments on civil penalties, and the role of the examining official in recommending civil penalties to the assessing official, we concluded that the proposed rule did not make it clear that the Initial Notice of Assessment would include a proposed civil monetary penalty. We have clarified the provisions of § 92.15 to provide that the Initial Notice of Assessment will include a statement of the proposed penalty.

B. Discussion of Substantive Comments From Businesses, Trade Associations and Others Generally

Six of the comments that the United States Mint received were from small businesses involved in the coin business. Each of these commenters expressed concern over the proposed regulation, with several expressing direct opposition. Two expressed general support for the regulation.

1. Fairness Comments

The United States Mint acknowledges the perception of several commenters that the proposed regulation may not be fairly enforced because the United States Mint sells United States coinage and, under the regulation, would have the power to take action against private businesses whose advertisements and solicitations misuse the names, symbols

and indicia of the United States Mint or the United States Treasury Department.

Several commenters expressed concern about the role of the United States Mint's Director as the decision maker under the regulation. One commenter raised the issue of whether the United States Mint's Director can be considered an impartial decision maker. Another commenter alleged that the regulations were unfair in that they gave the United States Mint, a competitor in the marketing of legal tender coinage, discretion to assess civil penalties against its own competitors. This, it stated, ''creat[ed] a situation that is intrinsically unfair and open to abuse.''

We note, however, that there is no inherent conflict of interest in having the United States Mint policing the improper use of the United States Mint's and the Treasury Department's names and symbols. The owner of intellectual property has the responsibility of protecting that property from improper use; this doctrine is codified and well recognized in the body of Federal intellectual property law. Additionally, no United States Mint or Treasury Department official who could have a role in the execution of the regulation has any official duty that inherently conflicts with the interests that the regulation is designed to protect. The authority of a Government agency to assess fines, in accordance with the authority and procedures established under law, naturally requires officials of that agency to act fairly, impartially, and judiciously. Every United States Mint and Treasury Department official—like all Government officials—has a duty to avoid conflicts of interest, act impartially, not give preferential treatment, protect and conserve public property, and adhere to the law. 5 CFR 2635.101. These duties are not inconsistent with these officials' fiduciary responsibility to protect public funds. Although it is true that the United States Mint generates revenues through the sale of numismatic items, the United States Mint is a Federal agency—not a commercial enterprise. By law, any amount in the United States Mint Public Enterprise Fund that is determined to be in excess of the amount required by the Fund, including the proceeds of fines assessed under the regulation, shall be transferred to the Treasury for deposit as miscellaneous receipts. See 31 U.S.C. 5136. Accordingly, fines paid under the regulation are not analogous to profit generated by a private company; they do not accrue to the benefit of either the United States Mint or its officials but, rather, to the General Treasury.

2. Economic Interest Comments

One commenter stated, ''These regulations will be enforced by government officials who have an economic interest in the results of the enforcement proceedings.'' Contrary to the comment, neither the examining official nor the assessing official will have any economic interest in the results of enforcement proceedings under this subpart. Employee compensation for all United States Mint employees is not based upon the United States Mint's coin sales or revenue. The United States Mint has performance awards and incentives that do affect compensation; however, these are based on criteria relating to the United States Mint's efficiency of operations and reductions in overhead and other costs. Civil penalties assessed under this regulation affect none of these criteria.

3. Competition Comments

Several commenters expressed the concern that the United States Mint would use its enforcement ability under the regulation in an unfair manner. One stated, ''The regulation gives the Mint too much power to unfairly pick and choose the competitors it wishes to punish.'' Another stated, ''We are concerned about the Mint's path on trying to eliminate competition with regulations and unfair enforcement actions.'' The United States Mint, in proposing and enacting these regulations, does not seek to ''eliminate competition'' but, rather, seeks to reduce consumer confusion and deceptive practices. Under Federal law, the United States Mint is the only entity permitted to produce United States coinage. As a Government monopoly, the United States Mint does not have competition in producing legal tender coinage for the United States. The purpose of the proposed rule, therefore, is not to eliminate competition but, instead, to protect consumers, collectors and the public from the improper use of Treasury and United States Mint names and symbols.

This protection is necessary because third parties increasingly have engaged in marketing practices that have the potential to mislead consumers by using the United States Mint's and Treasury Department's name and symbols with products not produced by either the United States Mint or the Treasury Department. More specifically, the United States Mint is aware of advertisements that have used the United States Mint's name and symbols in marketing tokens and medals not produced by the United States Mint. These tokens and medals are designed to resemble the designs of United States legal tender coinage despite the fact that tokens and medals have no status as legal tender in the United States. The United States Mint is also aware that other parties have acquired coinage and numismatic items produced by the United States Mint, have altered them (usually by plating and coloring them), and then have advertised the resulting items for sale as products of the United States Mint. We view these practices as being deceptive because, in both instances, the use of the United States Mint's and the Treasury Department's names and symbols in these contexts conveys the false impression that the advertisement, product or activity is endorsed, sponsored or affiliated with the United States Mint or the Treasury Department. The goal of the United States Mint in enacting these regulations is simply to prevent the deceptive misuse of the Treasury Department's and the United States Mint's names and symbols by third parties.

4. Comments on the Use of Disclaimers

Two commenters also expressed concern over the provision in the proposed regulations that disclaimers will not be considered when determining whether an advertisement is misusing a United States Mint or Treasury Department name or symbol. One commented, ''If a company has an advertisement for the sale of U.S. Mint coins, but clearly states that it is not affiliated, endorsed or authorized by the U.S. Mint, the regulation states that the disclaimers will be ignored. This makes no sense.''

Similarly, the Federal Trade Commission's staff comment, in part, addressed the proposed rule's treatment of disclaimers of affiliation and indicated, ''The proposed rule's treatment of disclaimers of affiliation in this process may raise some potential legal and policy issues.'' The comment then set forth the FTC's approach to reviewing advertising claims.

We note, however, that the statute upon which the regulation is based specifically addresses disclaimers. It states the following:

(b) Treatment of Disclaimers.

Any determination of whether a person has violated the provisions of subsection (a) shall be made without regard to any use of a disclaimer of affiliation with the United States Government or any particular agency or instrumentality thereof.

31 U.S.C. 333(b).

Given the clear requirement in 31 U.S.C. 333(b) that a determination of a violation be made without regard to any use of a disclaimer of affiliation, this

requirement cannot be removed from the regulation.

We believe, however, that it is appropriate to consider the use of a disclaimer as a factor in determining the amount of any civil penalty that the Assessing Official imposes under the regulation. If the disclaimer is clear and prominent and is likely to be noticed by a consumer and is not contradicted or confused by any claims made in the materials found to be in violation of 31 U.S.C. 333, then the Examining Official may propose, and the Assessing Official may assess, a civil penalty in an amount lower than that which would otherwise be appropriate, including, where warranted, a penalty in a nominal amount.

C. Discussion of Substantive Comments From Trade Associations in Particular

The remaining comments were submitted by two trade associations. The Magazine Publishers of America, while supporting the proposed rule, indicated its concern ''that the proposed rule may inadvertently impose liability on publishers and other media that, through no fault of their own, disseminate false advertisements.'' The Magazine Publishers of America requested that an exception be included in the final rule ''to exempt the media from fines * * * associated with false advertising.'' The Magazine Publishers of America also cited several Federal statutes, court decisions and state statutes in which media publishers were not held responsible for the content of advertisements from parties who purchased advertising space in their publications.

After considering these comments, we concur that publishers of newspapers, magazines, and other broadcasters of media, who merely sell advertising space to third parties should not be held responsible for ensuring compliance with the rule proposed by the United States Mint. The rule focuses on the person who ''uses'' the operable words, letters, symbols, or emblems in connection with, or as part of, an advertisement, solicitation, business activity, or product; the rule does not focus on a party who makes space available to the using person. Accordingly, we believe that the rule could not be applied to assess a penalty against a publisher or broadcaster that merely sells space and has no responsibility for the substantive content of an advertisement. However, we do not believe that amending the rule to excuse publishers or broadcasters from liability under all possible circumstances is appropriate. Rather, in each case, the examining and assessing officials will look to the extent of the publisher's or broadcaster's participation in the preparation of the challenged advertisement, solicitation, or business activity, and whether the publisher or broadcaster knew or should have known during that preparation process that the advertisement, solicitation, or business activity included improper uses of names, emblems, or symbols covered by 31 U.S.C. 333 and the rule. Finally, we note that the same definition of ''person'' has appeared at 31 CFR 27.2(f) (the Treasury Department regulation implementing 31 U.S.C. 333) since 1997 with no reported action against any publisher or broadcaster.

The other trade association submitting comments was the Industry Council for Tangible Assets (ICTA), a trade association for rare coin and precious metals dealers. In summary, the ICTA believes the proposed regulations: (1) ''exceed the mandate of 31 U.S.C. 333 by adding 'trademark' to the scope of the regulation''; (2) ''[are] overly broad and will deny due process to those who directly compete with the Mint''; (3) ''raise serious concerns about violations of commercial free speech protected by the first amendment''; and (4) ''are flawed in their failure to allow for a reasonable period to cure alleged violations.'' The ICTA comments also indicate that ''existing law provides the Mint with adequate remedies for perceived problems and there are more appropriate regulations that could be proposed to accomplish the goals of the Mint.'' The Professional Numismatics Guild sent a letter expressing its support for the comments made by the ICTA.

1. Use of the Word ''Trademark'' in the Definition of ''Symbol''

The ICTA asserts that the United States Mint has ''exceeded the mandate of 31 U.S.C. 333 by adding 'trademark' to the scope of the regulation.'' It also asserts that United States Mint's definition of the phrase ''symbol'' under the regulation ''facially appears to go beyond the scope of 31 U.S.C. 333(c)'' as it includes ''a trademark, designation of origin, or mark of identification.'' ITCA Comment at 13.

An examination of the statute, 31 U.S.C. 333, shows that the word ''symbol'' occurs in two places in subsection (a) although the statute does not define the term. The statute uses the term ''symbol'' in section (a) stating the following:

> No person may use, in connection with, or as a part of, any advertisement, solicitation, business activity or product, whether alone or with other words, letters, *symbols* or emblems. * * *

The United States Mint's proposed regulation closely tracked the language of the statute in subsection (a). The United States Mint's proposed regulation, however, defined the term ''symbol'' as ''any letter, word, number, picture, design, graphic or any combination thereof used by the United States Mint or the Treasury Department as a trademark, designation of origin, or mark of identification.'' See Proposed Regulation, section 92.12(i).

It is well-established that words in a statute are to be given their common, ordinary meaning. *See Federal Deposit Ins. Corp.* v. *Meyer*, 114 S. Ct. 996, 1000 (1994); *Director, Office of Workers' Compensation Programs* v. *Greenwich Collieries*, 114 S. Ct. 2251, 2255 (1994). The word ''symbol'' has been commonly defined as ''[s]omething that represents something else by association, resemblance, or convention, especially a material object used to represent something invisible.'' American Heritage Dictionary of the English Language (4th ed. 2006). Similarly, under the Lanham Trademark Act, trademarks ''includ[e] any word, name, symbol, or device, or any combination thereof adopted and used by a manufacturer or merchant to identify his goods and distinguish them from those manufactured or sold by others.'' 15 U.S.C. 1127. Because of the close association between the word ''symbol'' and the definition of trademark, we believe including trademarks as part of the definition of symbol in the final rule is a reasonable construction of the statute. *See Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984) (noting that ''considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer'').

The United States Mint, however, has decided to modify slightly the definition of the word ''symbol'' in the final rule for clarity. Hence, ''symbol'' is now defined as ''any design or graphic used by the United States Mint or the Treasury Department to represent themselves or their products.'' It further clarifies that a ''design or graphic may include (1) a trademark, designation of origin, or mark of identification, or (2) a stylized depiction comprising letters, words, or numbers.''

2. Assertion That the Proposed Rule Is ''Overly Broad'' and ''Violates Due Process''

The ICTA, secondly, asserts that the proposed rule ''[is] overly broad and will deny due process to those who directly compete with the Mint.'' After

reviewing the proposed regulation and the enabling statute, we believe the regulation is narrowly drawn and is not overly broad. The proposed regulation closely tracks each of the elements of the enabling statute. The only new material sets forth the procedures being adopted for imposing a civil penalty. These procedures include written notice of any potential violations, an opportunity to respond, consideration of any response, a written decision with an evaluation of each penalty factor, and a right of appeal to any person found to have violated the regulation. These procedures, in our view, fully comply with applicable due process requirements.

3. Concern That the Rule Violates the First Amendment

The ITCA commented that the proposed regulation ''threaten[s] the freedom of commercial speech under the First Amendment.'' In particular, the ITCA indicated that ''the regulations fail the Supreme Court's *Central Hudson* test because they are over broad.'' In *Central Hudson Gas* v. *Public Service Comm. of New York*, 447 U.S. 557, 563–64 (1980), however, the United States Supreme Court noted that ''there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity.'' The Court also made it clear that ''[t]he government may ban forms of communication more likely to deceive the public than to inform it'' Id. (citing *Friedman* v. *Rogers*, 440 U.S. 1, 13, 15–16 (1979); *Ohralik* v. *Ohio State Bar Assn.*, 436 U.S. 447, 464–65 (1978)). In light of this passage from *Central Hudson*, we do not believe the regulation violates any commercial free speech right under the First Amendment. To the contrary, the regulation implements a law that functions precisely in the manner to which the *Central Hudson* Court stated that ''there could be no constitutional objection.'' Specifically, 31 U.S.C. 333 effectively ''ban[s] forms of communication more likely to deceive the public than to inform it'': the misuse of Department of the Treasury or United States Mint names, titles, abbreviations, initials, symbols, or emblems in a manner that conveys a false impression.

4. Concern About Providing a Reasonable Period To Cure Alleged Violations

The ICTA asserted that the proposed regulations ''are flawed in their failure to allow for a reasonable period to cure alleged violations.'' However, the statute does not provide for, nor does it require the agency to afford to an offending party, a cure period. Indeed, we note that another part of the statute (31 U.S.C. 333(d)) provides for criminal penalties for precisely the same offenses over which the agency would exercise civil penalty authority. Although a notice of assessment naturally would put an alleged offending party on notice that it immediately should consider steps to cure the alleged misuse, the inherent purpose for the statute is to allow the agency to penalize the offending party for the misuse. In light of this concern, however, the United States Mint has modified the final regulation slightly so that it expressly requires the examining and assessing officials to consider the repeated nature of the misuse in determining whether, and to what extent, a penalty should be imposed against an offending party.

D. Comments on Impartiality

Some of the commenters pointed out that if the Government seeks to infringe upon a citizen's liberty, it ''always has the obligation of providing a neutral decision-maker—one who is not inherently biased against the individual or who has personal interest in the outcome.'' *Tumey* v. *Ohio*, 273 U.S. 510, 532 (1927). We acknowledge the commenters' concern about impartiality, but conclude that the proposed regulations fully comply with the agency's obligations in this respect.

In general, ''[t]he mere fact that an administrative or adjudicative body derives a financial benefit from fines or penalties that it imposes is not in general a violation of due process * * *.'' *Van Harkin* v. *City of Chicago*, 103 F.3d 1346 at 1348 (7th Cir. 1997) (citing *Dugan* v. *Ohio*, 277 U.S. 61 (1928)); *see Commonwealth of the Northern Mariana Islands* v. *Kaipat*, 94 F.3d 574, 580–81 (9th Cir. 1996); *Doolin Security Savings Bank* v. *Federal Deposit Ins. Corp.*, 53 F.3d 1395, 1405–07 (4th Cir. 1995). Moreover, in Doolin, the Fourth Circuit recognized that, although most Federal agencies have some form of institutional bias, this does not make them incapable of disinterested adjudication of disputes. 53 F.3d at 1407.

We do not believe the regulation raises issues of impartiality. First, the Director of the United States Mint has no personal or official economic interest in the results of any enforcement action under this regulation. Pursuant to the United States Mint Public Enterprise Fund (PEF) statute, 31 U.S.C. 5136, all receipts from fines assessed under the regulation would be deposited in the PEF and the Secretary of the Treasury would transfer these amounts, along with regular United States Mint seigniorage and profits, to the General Fund as miscellaneous receipts. As miscellaneous receipts in the Treasury—the drawing of funds from which are subject to appropriation by Congress—neither the Secretary of the Treasury, nor the Director of the Mint could be subject to ''possible temptation * * * when [their] executive responsibilities * * * may make [them] partisan to maintain the high level of contribution'' from the assessment process provided for under the regulation. *Cf. Ward* v. *Village of Monroeville*, 409 U.S. 57, 60 (1972). Moreover, the amounts involved would nonetheless render any ostensible temptation inconsequential because the relatively small amounts that the United States Mint could be expected to receive in fines payable under 31 U.S.C. 333 would be *de minimis* when compared to the recent amounts ($600–800 million) that the United States Mint annually has transferred to the General Fund. *See* 2006 United States Mint Annual Report, at 17. Accordingly, for the reasons described above, as well as in paragraphs III(b)(1) and (2), the United States Mint has no intrinsic bias that may affect its ability to adjudicate matters under this regulation in a fair and objective manner.

IV. Additional Amendments

Upon additional review and consideration of the provisions outlined in the interim rule, the agency has removed from the regulation sections 92.16(d)(3) & (4), which provide for agency counsel review. We also made conforming changes to section 92.17(a). The agency determined that these steps in the examination and assessment process are best addressed through internal procedures.

We also have made minor clarifying changes throughout the final rule.

V. Procedural Requirements

This final rule is not a significant regulatory action for the purposes of Executive Order 12866. While a proposed rule was published for public comment, the rule establishes agency practice and procedure, and prior notice and the opportunity for public comment were not required pursuant to 5 U.S.C. 553(b)(A) (or any other law). For this reason, a Regulatory Flexibility Act analysis is not required. *See* 5 U.S.C. 604. Nonetheless, it is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities. Any imposition of a civil penalty on a small business entity flows directly from the authorizing statute, 31 U.S.C. 333.

Paperwork Reduction Act

The final rule does not require new ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995. The only information collected would be that provided voluntarily by persons sent Initial Notices of Assessment under the regulation.

VI. Format

The format of the final rule is generally consistent with the format of the rule proposed in the NPRM.

List of Subjects in 31 CFR Part 92

Administrative practice and procedure, Advertising, Consumer protection, Currency, Penalties, Seals and insignia, Signs and symbols, Trademarks.

Text of Rule

■ For the reasons set forth in the preamble, the United States Mint amends 31 CFR part 92 as follows:

PART 92—UNITED STATES MINT OPERATIONS AND PROCEDURES

■ 1. The authority citation for part 92 is revised to read as follows:

Authority: 5 U.S.C. 301, 31 U.S.C. 321 and 333.

■ 2. The heading for part 92 is revised to read as set forth above.

■ 3. Add a subpart heading before § 92.1 to read as follows:

Subpart A—Numismatic Operations

■ 4. Add a subpart heading before § 92.5 to read as follows:

Subpart B—Availability of Records

■ 5. Add a new Subpart C (§§ 92.11 through 92.18) to read as follows:

Subpart C—Assessment of Civil Penalties for Misuse of Words, Letters, Symbols, or Emblems of the United States Mint

Sec.

92.11 Purpose.
92.12 Definitions.
92.13 Assessment of civil penalties.
92.14 Initiation of action.
92.15 Initial notice of assessment.
92.16 Written response.
92.17 Final action.
92.18 Judicial review.

Subpart C—Assessment of Civil Penalties for Misuse of Words, Letters, Symbols, or Emblems of the United States Mint

§ 92.11 Purpose.

(a) The procedures in this subpart implement the provisions of 31 U.S.C. 333(c), which authorize the Secretary of the Treasury to assess a civil penalty against any person who has misused the words, titles, abbreviations, initials, symbols, emblems, seals, or badges of the United States Mint in violation of 31 U.S.C. 333(a).

(b) The procedures in this subpart do not apply to the extent that the Secretary of the Treasury, the Director of the United States Mint, or their authorized designees have specifically granted to the person express permission, in writing, to manufacture, produce, sell, possess, or use the words, titles, abbreviations, initials, symbols, emblems, seals, or badges in a contract, agreement, license, letter, memorandum, or similar document.

(c) The procedures in this subpart are limited to actions initiated by the United States Mint to enforce the provisions of 31 U.S.C. 333. The procedures herein do not affect the provisions of 31 CFR Part 27. Therefore, this subpart shall not be construed as the exclusive means for the Secretary of the Treasury to enforce 31 U.S.C. 333 insofar as a covered misuse affects the United States Mint.

§ 92.12 Definitions.

(a) *Assessing official* means the Director of the United States Mint or his designee.

(b) *Examining official* means an employee of the United States Mint appointed by the Director of the United States Mint (or an employee of the Treasury Department appointed by the Director of the United States Mint with the concurrence of the head of that employee's organization), to administer the procedures in this subpart in a particular case and to propose findings and recommendations in that case to the assessing official. The examining official must be:

(1) An employee of the Treasury Department in the grade of GS–15 or higher; and

(2) Capable of examining the matter without actual or apparent conflict of interest.

(c) *Broadcast* or *telecast* means widespread dissemination by electronic transmission or method, whether audio and/or visual.

(d) *Civil penalty* means a civil monetary penalty

(e) *Date of offense* means the later of:

(1) The date that the misuse occurred;

(2) The date that the misuse had the effect of conveying the false impression that the activity was associated with or approved, endorsed, sponsored or authorized by the United States Mint or its officers or employees; or

(3) If the violation is a continuing one, the date on which the misuse of the words, titles, abbreviations, initials, symbols, emblems, seals, or badges protected by 31 U.S.C. 333 or the procedures in this subpart last occurred.

(f) *Days* means calendar days, unless otherwise stated.

(g) *Person* means an individual, partnership, association, corporation, company, business, firm, manufacturer, or any other organization, entity, or institution.

(h) *Respondent* means a person named in an Initial Notice of Assessment.

(i) *Symbol* means any design or graphic used by the United States Mint or the Treasury Department to represent themselves or their products. A design or graphic may include

(1) A trademark, designation of origin, or mark of identification, or

(2) A stylized depiction comprising letters, words, or numbers.

§ 92.13 Assessment of civil penalties.

(a) *General rule.* The assessing official may impose a civil penalty on any person when the following two conditions are met:

(1) That person uses in connection with, or as a part of, any advertisement, solicitation, business activity, or product, whether alone or with other words, letters, symbols, or emblems—

(i) The words ''Department of the Treasury,'' ''United States Mint,'' or ''U.S. Mint'';

(ii) The titles ''Secretary of the Treasury,'' ''Treasurer of the United States,'' ''Director of the United States Mint,'' or ''Director of the U.S. Mint'';

(iii) The abbreviations or initials of any entity or title referred to in paragraph (a)(1)(i) or (a)(1)(ii) of this section;

(iv) Any symbol, emblem, seal, or badge of an entity referred to in paragraph (a)(1)(i) of this section (including the design of any envelope, stationery, or identification card used by such an entity); or

(v) Any colorable imitation of any such words, titles, abbreviations, initials, symbols, emblems, seals, or badges; and

(2) That person's use is in a manner that could reasonably be interpreted or construed as conveying the false impression that such advertisement, solicitation, business activity, or product is in any manner approved, endorsed, sponsored, authorized by, or associated with the United States Mint, or any officer, or employee thereof.

(b) *Disclaimers.* Any determination of whether a person has violated the provisions of paragraph (a) of this section shall be made without regard to any use of a disclaimer of affiliation

with the United States Government or any particular agency or instrumentality thereof.

(c) *Civil penalty*. The assessing official may impose a civil penalty on any person who violates the provisions of paragraph (a) of this section. The amount of a civil penalty shall not exceed $5,000 for each and every use of any material in violation of paragraph (a) of this section, except that such penalty shall not exceed $25,000 for each and every use if such use is in a broadcast or telecast.

(d) *Time limitations*. (1) Civil penalties imposed under the procedures in this subpart must be assessed before the end of the three-year period beginning on the date of offense.

(2) The assessing official may commence a civil action to recover or enforce any civil penalty imposed in a Final Notice of Assessment issued pursuant to § 92.17 at any time before the end of the two-year period beginning on the date of the Final Notice of Assessment. If judicial review of the Final Notice of Assessment is sought, the two-year period begins to run from the date that a final and unappealable court order is issued.

(e) *Criminal Proceeding*. No civil penalty may be imposed under the procedures in this subpart with respect to any violation of paragraph (a) of this section after a criminal proceeding on the same violation has been commenced by indictment or information under 31 U.S.C. 333(d).

§ 92.14 Initiation of action.

(a) When an employee of the United States Mint learns of or discovers a potential violation of 31 U.S.C. 333 or this subpart, he or she will refer the matter, with all available evidence, to the assessing official.

(b) The assessing official will consider relevant factors when determining whether to initiate an action to impose a civil penalty under the procedures in this subpart. Those factors may include, but are not limited to, the following:

(1) The scope of the misuse;

(2) The purpose and/or nature of the misuse;

(3) The extent of the harm caused by the misuse;

(4) The circumstances of the misuse;

(5) The commercial benefit intended to be derived from the misuse; and

(6) The repeated nature of the misuse.

(c) If the assessing official decides to initiate an action to impose a civil penalty under the procedures in this subpart, he or she will, in writing:

(1) Appoint an examining official; and

(2) Delegate to the examining official the authority to prepare, sign, and serve an Initial Notice of Assessment on behalf of the assessing official.

§ 92.15 Initial notice of assessment.

The examining official shall review all immediately available evidence on the matter; determine a proposed civil penalty based on the factors listed under § 92.16(d)(2)(iii); and prepare and serve an Initial Notice of Assessment by United States mail or other means upon the person believed to be in violation of § 92.13 and otherwise subject to a civil penalty. The notice shall provide the name and telephone number of the examining official, who can provide information concerning the notice and the procedures in this subpart. The notice shall include the following:

(a) A specific reference to the provisions of § 92.13 violated;

(b) A concise statement of the facts that support the conclusion that such a violation occurred;

(c) The amount of the civil penalty proposed and the maximum amount of the potential civil penalty that the assessing official could impose;

(d) A notice informing the person alleged to be in violation of § 92.13 that he or she:

(1) May, within 30 days of the date of the notice, pay the proposed civil penalty, thereby waiving the right to make a written response under § 92.16 and to seek judicial review under § 92.18:

(i) By electronic funds transfer (EFT) in accordance with instructions provided by the examining official in the Initial Notice of Assessment; or

(ii) By means other than EFT only with the written approval of the assessing official;

(2) May make a written response in accordance with § 92.16 within 30 days of the date of the notice addressing, as appropriate:

(i) Why a civil penalty should not be imposed; and

(ii) Why a civil penalty should be in a lesser amount than proposed.

(3) May be represented by an attorney or other representative, provided that a designation of representative signed by the person alleged to be in violation is received by the examining official; and

(4) May request, within 20 days of the date of the notice, a copy of or opportunity to review any documents and/or other evidence that the United States Mint compiled and relied on in determining to issue the notice (the assessing official reserves the right to assert privileges available under law and may decline to disclose certain documents and/or other evidence protected by such privileges; however, any documents or other evidence withheld from disclosure shall be expunged from the record and shall not be considered by the examining and assessing officials in arriving at their respective recommendations and decisions); and

(e) An advisement of the following:

(1) If no written response is received within the time allowed in § 92.16(b), a Final Notice of Assessment may be issued without a presentation by the person;

(2) If a written response has been made and the examining official deems it necessary, the examining official may request, orally or in writing, additional information from the respondent;

(3) A Final Notice of Assessment may be issued in accordance with § 92.17 requiring that the proposed civil penalty be paid;

(4) A Final Notice of Assessment is subject to judicial review in accordance with 5 U.S.C. 701 *et seq.*; and

(5) All submissions sent in response to the Initial Notice of Assessment must be transmitted to the address specified in the notice and include the name, address, and telephone number of the respondent.

§ 92.16 Written response.

(a) *Form and contents*. (1) The written response submitted by a person pursuant to § 92.15(d)(2) must provide the following:

(i) A reference to and specific identification of the Initial Notice of Assessment involved;

(ii) The full name of the person against whom the Initial Notice of Assessment has been made;

(iii) If the respondent is not a natural person, the name and title of the officer authorized to act on behalf of the respondent; and

(iv) If a representative of the person named in the Initial Notice of Assessment is filing the written response, a copy of the duly executed designation as representative.

(2) The written response must admit or deny each violation of § 92.13 set forth in the Initial Notice of Assessment. Any violation not specifically denied will be presumed to be admitted. Where a violation is denied, the respondent shall specifically set forth the legal or factual basis upon which the allegation is denied. If the basis of the written response is that the respondent is not the person responsible for the alleged violation, the written response must set forth sufficient information to allow the examining and assessing officials to determine the truth of such an assertion. The written response should include any and all documents and other information that the respondent believes

should be a part of the administrative record on the matter.

(b) *Time.* (1) Except as provided in paragraph (b)(2) of this section, any written response made under this section must be submitted not later than 30 days after the date of the Initial Notice of Assessment.

(2) If a request for documents or other evidence is made pursuant to § 92.15(d)(4), the written response must be submitted not later than 20 days after the date of the United States Mint's response to the request.

(3)(i) In computing the number of days allowed for filing a written response under this paragraph, the first day counted is the day after the date of the Initial Notice of Assessment is issued. If the last date on which the response is required to be filed by this paragraph is a Saturday, Sunday or Federal holiday, the response will be due on the next business day after that date.

(ii) If a response is transmitted by United States mail, it will be deemed timely filed if postmarked on or before the due date.

(4) The examining official may extend the period for making a written response under paragraphs (b)(1) and (b)(2) of this section for up to ten days for good cause shown. Requests for extensions beyond ten days must be approved by the assessing official and must be based on good cause shown. Generally, failure to obtain representation in a timely manner will not be considered good cause.

(c) *Filing.* The response may be sent by personal delivery, United States mail or commercial delivery. A written response transmitted by means other than United States mail will be considered filed on the date received at the address specified in the Initial Notice of Assessment.

(d) *Review and Recommendation.* The examining official will fully consider the facts and arguments submitted by the respondent in the written response, any other documents filed by the respondent pursuant to this subpart, and the evidence in the United States Mint's record on the matter. If the respondent waives the right to submit a written response in accordance with § 92.15(d)(1), or declines to submit a written response by the end of the 30-day response period, the examining official will fully consider the evidence in the United States Mint's record on the matter.

(1) In fully considering the matter, the examining official will not consider any evidence introduced into the record by the United States Mint after the date of the Initial Notice of Assessment unless and until the respondent has been notified that such additional evidence will be considered, and has had an opportunity to request, review and comment on such evidence.

(2) The examining official will prepare a concise report, addressed to the assessing official, which will contain the following:

(i) The entire administrative record on the matter, including all information provided in or with a written response timely filed by the respondent and any additional information provided pursuant to § 92.15(e)(2), as well as all evidence upon which the Initial Notice of Assessment was based, and any additional evidence as provided for in § 92.16(d)(1).

(ii) A finding, based on the preponderance of the evidence, as to each alleged violation specified in the Initial Notice of Assessment;

(iii) For each violation that the examining official determines to have occurred, a recommendation as to the appropriate amount of a civil penalty to be imposed which, upon additional consideration of the evidence, may be the same as, more than, or less than the amount initially proposed by the examining official pursuant to § 92.15. In making this recommendation, the examining official will consider all relevant factors including, but not limited to, the following:

(A) The scope of the misuse;

(B) The purpose and/or nature of the misuse;

(C) The extent of the harm caused by the misuse;

(D) The circumstances of the misuse;

(E) The commercial benefit intended to be derived from the misuse; and

(F) The repeated nature of the misuse.

(iv) If the examining official determines that a violation has occurred, a proposed Final Notice of Assessment that incorporates his or her findings and recommendations.

(v) Any additional information or considerations that the assessing officer should consider in a decision whether to issue a Final Notice of Assessment under § 92.17.

§ 92.17 Final action.

(a) In making a final determination whether to impose a penalty, the assessing official shall take into consideration the entire report prepared by the examining official. Although the assessing official should accord appropriate weight to the findings and recommendations of the examining official, the assessing official is not bound by them. The assessing official may approve, disapprove, modify, or substitute any or all of the examining official's findings and recommendations if, in his or her judgment, the evidence in the record supports such a decision. The assessing official will determine whether:

(1) The facts warrant a conclusion that no violation has occurred; or

(2)(i) The facts warrant a conclusion that one or more violations have occurred; and

(ii) The facts and violations found justify the conclusion that a civil penalty should be imposed.

(b) If the assessing official determines that no violation has occurred, the official shall promptly send a letter indicating that determination to the person served with an Initial Notice of Assessment and to any designated representative of such person.

(c) If the assessing official determines that a violation has occurred:

(1) The assessing official shall issue a Final Notice of Assessment to the person served with an Initial Notice of Assessment and to any designated representative of such person.

(2) The assessing official may, in his or her discretion:

(i) Impose a civil penalty;

(ii) Not impose a civil penalty; or

(iii) Impose a civil penalty and suspend the payment of all or some of the civil penalty, conditioned on the violator's future compliance with 31 U.S.C. 333.

(3) If a civil penalty is imposed under § 92.17(c)(2)(i) or (iii), the assessing official shall determine the appropriate amount of the penalty in accordance with 31 U.S.C. 333(c)(2). In determining the amount of a civil penalty, the assessing official will consider relevant factors including, but not limited to, the following:

(i) The scope of the misuse;

(ii) The purpose and/or nature of the misuse;

(iii) The extent of the harm caused by the misuse;

(iv) The circumstances of the misuse;

(v) The commercial benefit intended to be derived from the misuse; and

(vi) The repeated nature of the misuse.

(4) The Final Notice of Assessment shall:

(i) Include the following:

(A) A specific reference to each provision of § 92.13 found to have been violated;

(B) A concise statement of the facts supporting a conclusion that each violation has occurred;

(C) An analysis of how the facts and each violation justifies the conclusion that a civil penalty should be imposed; and

(D) The amount of each civil penalty imposed and a statement as to how the

amount of each penalty was determined; and

(ii) Inform the person of the following:

(A) Payment of a civil penalty imposed by the Final Notice of Assessment must be made within 30 days of the date of the notice;

(B) Payment of a civil penalty imposed by the Final Notice of Assessment shall be paid by EFT in accordance with instructions provided in the notice, unless the assessing official has given written approval to have payment made by other means;

(C) If payment of a civil penalty imposed by the Final Notice of Assessment has been suspended on the condition that the person comply in the future with 31 U.S.C. 333 and this subpart, the failure by the person to so comply will make the civil penalty payable on demand;

(D) If a civil penalty is not paid within 30 days of the date of the Final Notice of Assessment (or on demand under paragraph (c)(3)(ii)(D) of this section), a civil action to collect the penalty or enforce compliance may be commenced at any time within two years of the date of the Final Notice of Assessment; and

(E) Any civil penalty imposed by the Final Notice of Assessment may be subject to judicial review in accordance with 5 U.S.C. 701 *et seq.*

§ 92.18 Judicial review.

A Final Notice of Assessment issued under the procedures in this subpart may be subject to judicial review pursuant to 5 U.S.C. 701 *et seq.*

Dated: October 22, 2007.

Edmund C. Moy,

Director, United States Mint.

[FR Doc. E7–21132 Filed 10–25–07; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. COTP Morgan City—07–018]

RIN 1625—AA00

Safety Zone; Morgan City-Port Allen Alternate Route, Mile Marker 0.5 to Mile Marker 1.0, Bank to Bank

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary Safety Zone on the Morgan City-Port Allen Alternate Route, from Mile Marker 0.5 to Mile Marker 1.0, bank to bank. This Safety Zone is needed to protect divers, vessels, and tows from destruction, loss, or injury from salvage operations to remove a crane from beneath the Long-Allen Fixed Bridge, and to facilitate compliance with a court approved Consent Judgment whereby the crane must be removed prior to December 1, 2007.

DATES: This rule is effective from 6 a.m. on October 29, 2007 until 6 p.m. on November 11, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of COTP Morgan City-07–018 and are available for inspection or copying at Marine Safety Unit Morgan City, 800 David Drive, Morgan City, Louisiana, 70380 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander (LCDR) Rick Paciorka, Marine Safety Unit Morgan City, at (985) 380–5320.

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**. Establishment of this safety zone is required to comply with a Consent Judgment approved by the Honorable Kurt D. Engelhardt, U.S. District Judge, in his order dated May 17, 2007. Pursuant to his Order, the Consent Judgment between Jefferson Marine Towing Inc., *et al* and the United States requires the crane to be removed by Jefferson Marine not later than 1 December 2007. In order to effect the Consent Judgment's court approved deadline, the U.S. Army Corps of Engineers (ACOE), the U.S. Coast Guard, and Jefferson Marine met to discuss the parameters of a salvage plan. This plan was preliminarily approved on 29 August 2007. The preliminary plan projected salvage operations beginning on 17 September 2007. Given the potential impact on the public and industry of this near term major waterway closure, the Coast Guard and the ACOE negotiated a later date beginning 29 October 2007. This later date allowed for transit planning that accommodates the vast majority of fall harvest barge movement while still allowing for completion of the salvage work by the court ordered deadline. The 29 October date was tentatively agreed upon on 13 September 2007. Publishing an NPRM and delaying its effective date would be contrary to public interest since immediate action is needed to protect divers, vessels, and mariners from the hazards associated with salvage operations in the area, and to facilitate compliance with the court approved Consent Judgment whereby the salvage operation must be concluded by 1 December 2007.

Background and Purpose

Due to an allision with the Long-Allen fixed bridge, a crane was lost from a barge into the Morgan City-Port Allen Alternate Route. Salvage operations will be conducted in the vicinity of the Long-Allen Fixed bridge to recover the crane. The Morgan City-Port Allen Alternate Route will be closed to marine traffic during salvage operations. This Safety Zone is needed to protect divers, vessels, and tows from destruction, loss or injury from the dangers associated with the salvage operations, and to facilitate compliance with a court approved Consent Judgment whereby the salvage operation must be concluded by 1 December 2007.

Discussion of Rule

The Coast Guard is establishing a temporary Safety Zone on the Morgan City-Port Allen Alternate Route, from Mile Marker 0.5 to Mile Marker 1.0, bank to bank. The temporary Safety Zone will continue in effect until the salvage operations are complete. Vessels and tows may not enter this zone while salvage operations are taking place. This rule is effective from 6 a.m. on October 29, 2007 until 6 p.m. on November 11, 2007.

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.

This rule will only be in effect for a 14 day period of time and notifications to the marine community will be made through broadcast notice to mariners. The impacts on routine navigation are expected to be moderate to great. Vessels may continue to transit through alternate routes to their destinations.

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. This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit through the Safety Zone from 6 a.m. CDT on October 29, 2007 until 6 p.m. CST on November 11, 2007. This Safety Zone will not have a significant economic impact on a substantial number of small entities because this rule will be in effect for a 14 day period of time. Additionally, vessels may continue to transit through alternate routes to their destinations.

If you are a small business entity and are significantly affected by this regulation, please contact LCDR Rick Paciorka, Marine Safety Unit Morgan City, at (985) 380–5320.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so they could better evaluate its effects on them and participate in the rulemaking process.

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 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. The Administrator of the Office of Information and Regulatory Affairs has not designated it as significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation because this rule is not expected to result in any significant adverse environmental impact as described in NEPA.

Under figure 2–1, paragraph (34)(g), of the Instruction, an ''Environmental Analysis Check List'' and a ''Categorical Exclusion Determination'' are not required for this rule.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary § 165.T08–018 is added to read as follows:

§ 165.T08–018 Safety Zone; Morgan City-Port Allen Alternate Route, from Mile Marker 0.5 to Mile Marker 1.0, bank to bank.

(a) *Enforcement Areas.* Morgan City-Port Allen Alternate Route, from Mile Marker 0.5 to Mile Marker 1.0, bank to bank.

(b) *Effective date.* This section is effective from 6 a.m. on October 29, 2007 until 6 p.m. on November 11, 2007.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.33 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port Morgan City.

(2) Vessels requiring entry into or passage through the Safety Zone must

request permission from the Captain of the Port Morgan City, or a designated representative. They may be contacted on VHF Channel 11, or by telephone at (985) 380–5320.

(3) All persons and vessels shall comply with the instructions of the Captain of the Port Morgan City and designated on-scene U.S. Coast Guard patrol personnel. On-scene U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast Guard.

Dated: October 23, 2007.

J. Scott Paradis,

Captain, U.S. Coast Guard, Captain of the Port Morgan City.

[FR Doc. 07–5354 Filed 10–24–07; 1:09 pm]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2007–0192; FRL–8486–6]

Approval and Promulgation of Air Quality Implementation Plans; Michigan; Consumer Products Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a request submitted by the Michigan Department of Environmental Quality (MDEQ) on February 13, 2007, to revise the Michigan State Implementation Plan (SIP). The state has requested approval of two rules in two areas of Part 6, Emission Limitations and Prohibitions-Existing Sources of Volatile Organic Compound (VOC) Emissions by adding R 336.1660, Standards for VOC Emissions from Consumer Products, by adopting by reference the Ozone Transport Commission's Model Rule with some modifications, and adding R 336.1661, Definitions for Consumer Products, to define VOC.

DATES: This direct final rule will be effective December 26, 2007, unless EPA receives adverse comments by November 26, 2007. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2007–0192, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: mooney.john@epa.gov.*

3. *Fax:* (312) 886–5824.

4. *Mail:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2007–0192. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. We recommend that you telephone Douglas Aburano, Environmental Engineer, at (312) 353–6960 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Douglas Aburano, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–6960, *aburano.douglas@epa.gov.*

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

I. Background
A. When did the State submit the requested rule revisions to EPA?
B. Did Michigan hold public hearings for each of these rule revisions?
II. What are the revisions that the State is requesting for incorporation into the SIP?
A. Standards for Volatile Organic Compounds Emissions from Consumer Products
B. Definitions for Consumer Products
III. What action is EPA taking?
IV. Statutory and Executive Order Reviews

I. Background

A. When did the State submit the requested rule revisions to EPA?

MDEQ submitted the requested rule revisions on February 13, 2007.

B. Did Michigan hold public hearings for each of these rule revisions?

MDEQ held hearings on July 10, 2006 and August 17, 2006, and did not receive any adverse comments.

II. What are the revisions that the State is requesting for incorporation into the SIP?

The State has requested the following revisions in Part 6, Emission Limitations and Prohibitions—Existing Sources of VOC Emissions: (1) Changes to R 336.1660, Standards for VOC Emissions from Consumer Products; and (2) changes to R 336.1661, Definitions for Consumer Products. The revisions are described in more detail below.

A. Standards for Volatile Organic Compounds Emissions from Consumer Products

MDEQ is requesting the addition of Part 6, R 336.1660, in which the state has adopted by reference the provisions in the Ozone Transport Commission's ''Model Rule for Consumer Products,'' dated March 6, 2001, with some modifications. The modifications are related to implementation dates that are updated from the Model Rule and include several other minor changes.

The rules limit the VOC content of consumer products, including personal care products, household products, automotive after-market products, adhesives and sealants, insecticides, coatings and related products (except architectural and maintenance coatings), and other miscellaneous products. The rules require that no person shall sell, supply, offer for sale, or manufacture for sale, in the state of Michigan, any of the affected consumer products (mostly aerosols and sprays), unless the VOC content limits specified in the Table of Standards of the rules are adhered to. Additionally, the rule has several other related requirements.

B. Definitions for Consumer Products

MDEQ is requesting the addition of Part 6, R 336.1661, in order to define VOC. R 336.1661 contains definitions used exclusively in R 336.1660.

III. What action is EPA taking?

We are approving revisions to the Michigan SIP in two portions of Part 6: (1) To add R 336.1660, Standards for VOC Emissions from Consumer Products, in which Michigan has adopted by reference the Ozone Transport Commission's Model Rule with some modifications, and (2) to add R 336.1661, Definitions for Consumer Products, to define VOC. Michigan has adopted the Model Rule by reference with two exceptions. Michigan did not adopt the sections that address violations and severability. It was not necessary for Michigan to adopt these two specific sections of the Model Rule as there are Michigan specific rules that already address these issues. Michigan Act 348, which is approved into the Michigan SIP, addresses violations. Section 324.9122 of Michigan Act 451 provides for severability of the State's rules.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective December 26, 2007 without further notice unless we receive relevant adverse written comments by November 26, 2007. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. If we do not receive any comments, this action will be effective December 26, 2007.

IV. Statutory and Executive Order Reviews

Executive Order 12866: Regulatory Planning and Review

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.

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

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

Regulatory Flexibility Act

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.*).

Unfunded Mandates Reform Act

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).

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (59 FR 22951, November 9, 2000).

Executive Order 13132: Federalism

This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely 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.

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

This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal Standard.

National Technology Transfer Advancement Act

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.

Paperwork Reduction Act

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.*).

Congressional Review Act

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 December 26, 2007. 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: October 11, 2007.

Walter W. Kovalick Jr.,

Acting Regional Administrator, Region 5.

■ 40 CFR part 52 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 X—Michigan

■ 2. In § 52.1170, the table in paragraph (c) entitled ''EPA-Approved Michigan Regulations'' is amended by adding entries in part 6 for ''R 336.1660'' and ''R 336.1661'' to read as follows:

§ 52.1170 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MICHIGAN REGULATIONS

Michigan citation	Title	State effective date	EPA approval date	Comments
*	*	*	*	*
Part 6. Emission Limitations and Prohibitions—Existing Sources of Volatile Organic Compound Emissions				
*	*	*	*	*
R 336.1660	Standards for Volatile Organic Compounds Emissions from Consumer Products.	1/29/07	10/26/07 [Insert page number where the document begins].	
R 336.1661	Definitions for Consumer Products.	1/29/07	10/26/07 [Insert page number where the document begins].	
*	*	*	*	*

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[FR Doc. E7–20948 Filed 10–25–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2007–0631; FRL–8486–4]

Approval and Promulgation of Implementation Plans; Michigan; Recordkeeping and Reporting Requirements for Abnormal Conditions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is approving Michigan's June 29, 2007, request to revise recordkeeping and reporting requirements for abnormal conditions, start-up, shutdown, and malfunction of a source, process, or process equipment. The revised rule contains more specific and complete recordkeeping and reporting requirements than are currently approved into the Michigan State Implementation Plan (SIP). In the proposed rules section of this **Federal Register**, EPA is proposing approval of and soliciting public comment on this requested SIP revision. If adverse comments are received on this action, EPA will withdraw this final rule and address the comments received in response to this action in a final rule on the related proposed. A second public comment period will not be held. Parties interested in commenting on this action should do so at this time.

DATES: This direct final rule will be effective December 26, 2007, unless EPA receives adverse comments by November 26, 2007. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2007–0631, by one of the following methods:

1. *http://www.regulations.gov:* Follow the online instructions for submitting comments.

2. *E-mail: mooney.john@epa.gov.*

3. *Fax:* (312) 886–5824.

4. *Mail:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR 18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR 18J), U.S.

Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2007–0631. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. We recommend that you telephone Kathleen D'Agostino, Environmental Engineer, at (312) 886–1767 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–1767, *dagostino.kathleen@epa.gov*.

SUPPLEMENTARY INFORMATION: In the following, whenever ''we,'' ''us,'' or ''our'' are used, we mean the United States Environmental Protection Agency.

Table of Contents

I. What Has Michigan Submitted?
II. What Action is EPA Taking?
III. Statutory and Executive Order Review

I. What Has Michigan Submitted?

On June 29, 2007, the Michigan Department of Environmental Quality (MDEQ) submitted a revision to the Michigan SIP. The submittal revises recordkeeping and reporting requirements for abnormal conditions, start-up, shutdown, and malfunction of a source, process, or process equipment contained in R 336.1912 of the Michigan Administrative Code. The revised rule contains more specific and complete recordkeeping and reporting requirements than are currently approved into the SIP.

The rule requires the owner or operator of a source to:

1. Operate in a manner consistent with good air pollution control practices for minimizing emissions during periods of abnormal conditions, start-up, shutdown, and malfunctions;

2. Provide notice of an abnormal condition, start-up, shutdown, or malfunction that results in the emission of a hazardous air pollutant or toxic air contaminant in excess of an emission standard which continues for more than one hour;

3. Provide notice and a written report of an abnormal condition, start-up, shutdown, or malfunction that results in emissions of any air contaminant continuing for more than two hours in excess of a standard or limitation;

4. Certify the truth, accuracy, and completeness of written reports; and

5. Incorporate into a preventative maintenance and malfunction abatement plan actions taken to correct and to prevent a reoccurrence of an abnormal condition or malfunction.

Notices, which can be by any reasonable means, including electronic, telephonic, or oral communication, are required to be submitted to the MDEQ no later than two business days after the start-up or shutdown or after discovery of the abnormal conditions or malfunction. Written reports are required to be submitted to the MDEQ within ten days after the start-up or shutdown occurred, within ten days after the abnormal conditions or malfunction has been corrected, or within thirty days of discovery of the abnormal conditions or malfunction, whichever is first.

Written reports must include the time and date, probable causes and duration of the abnormal conditions, start-up, shutdown, or malfunction; identification of the source, process, or process equipment involved; the type and, where possible, quantity or magnitude of the excess emissions; and information describing the measures taken and air pollution control practices followed to minimize emissions. For abnormal conditions and malfunctions, the report must also include a summary of the actions taken to correct and to prevent a reoccurrence of the abnormal conditions or malfunction and the time taken to correct the malfunction.

II. What Action Is EPA Taking?

EPA is approving R 336.1912 as a revision to the Michigan SIP. We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective December 26, 2007 without further notice unless we receive relevant adverse written comments by November 26, 2007. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. If we do not receive any comments, this action will be effective December 26, 2007.

III. Statutory and Executive Order Review

Executive Order 12866: Regulatory Planning and Review

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.

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

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

Regulatory Flexibility Act

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.*).

Unfunded Mandates Reform Act

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).

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (59 FR 22951, November 9, 2000).

Executive Order 13132: Federalism

This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely 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.

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

This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal Standard.

National Technology Transfer Advancement Act

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.

Paperwork Reduction Act

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.*).

Congressional Review Act

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 December 26, 2007. 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: October 10, 2007.

Walter W. Kovalick, Jr.,

Acting Regional Administrator, Region 5.

■ Parts 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 X—Michigan

■ 2. Section 52.1170(c) is amended by revising entry ''R 336.1912'' under part 9 to read as follows:

§ 52.1170 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MICHIGAN REGULATIONS

Michigan citation	Title	State effective date	EPA approval date	Comments
*	*	*	*	*
Part 9. Emission Limitations and Prohibitions—Miscellaneous				

EPA-APPROVED MICHIGAN REGULATIONS—Continued

Michigan citation	Title	State effective date	EPA approval date	Comments
*	* *	*	* *	*
R 336.1912	Abnormal conditions, start-up, shutdown, and malfunction of a source, process, or process equipment, operating, notification, and reporting requirements.	7/26/95, as corrected 6/1/07.	10/26/07 [Insert page number where the document begins].	
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[FR Doc. E7–20935 Filed 10–25–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1989–0007; FRL–8485–3]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of partial deletion of sites from the Otis Air National Guard Base/Camp Edwards Superfund Site from the National Priorities List.

SUMMARY: EPA New England Region (EPA) announces the deletion of 61 source area sites on the Otis Air National Guard Base/Camp Edwards Superfund Site from the National Priorities List (NPL). All 61 source area sites as listed in Table 1 were originally proposed for deletion (72 FR 41976) August 1, 2007, and encompass a total acreage of 482.1 acres. A source area site is defined by: soil; structures, if present; and does not include any contaminated groundwater plume that may be below the site. Otis Air National Guard Base/Camp Edwards is a Federal Facility Superfund Site known locally as the Massachusetts Military Reservation (MMR), so this notice will use MMR as the abbreviation to describe the entire Superfund Site. The United States Air Force is the lead agency at the MMR Superfund Site.

This partial deletion pertains to only the surface area of sites investigated (and in some cases cleaned-up) for soil contamination, and does not pertain to any of the 12 groundwater plumes associated with MMR Superfund Site. All other sites (including all contaminated groundwater plumes on the Site) not included in this notice will remain on the NPL. In the northern half of the MMR, there are source area sites and groundwater plumes associated with an investigation and cleanup program known as the Impact Area Groundwater Study Program which is being conducted under the authority of Safe Drinking Water Act Administrative Orders. These sites and groundwater plumes are not the subject of this partial deletion.

DATES: This partial deletion of the 61 source area sites on MMR is effective on October 26, 2007.

FOR FURTHER INFORMATION CONTACT: Bob Lim, Remedial Project Manager, U.S. Environmental Protection Agency, One Congress Street, Suite 1100 (HBT), Boston, Massachusetts 02114–2023, (617) 918–1392, Fax (617) 918–1291, e-mail: *lim.robert@epa.gov.*

SUPPLEMENTARY INFORMATION: Otis Air National Guard Base/Camp Edwards is a Federal Facility Superfund Site known locally as the Massachusetts Military Reservation (MMR), so this notice will use MMR as the abbreviation to describe the entire Superfund Site. MMR is located in portions of the towns of Bourne, Falmouth, Mashpee, and Sandwich.

This partial deletion pertains to the soil and, if present, structures at 61 sites ranging in size from half an acre to 80.7 acres. The total proposed area is 482.1 acres. Table 1 identifies structures as being present with an asterisk next to the site name. There would be 19 source area sites remaining. Even though some of the sites appear to be above contaminated groundwater plumes, this partial deletion does not include any plumes of contaminated groundwater because data shows that the sites are not related to the plumes. Currently eleven groundwater pump and treat cleanup remedies will continue operating until cleanup goals are met. In the northern half of MMR, there is a separate, ongoing investigation and cleanup program known as the Impact Area Groundwater Study Program (IAGWSP). These sites and groundwater plumes are not the subject of this Notice of Intent for Partial Deletion.

On August 1, 2007, EPA published a Notice of Intent for Partial Deletion in the **Federal Register** (72 FR 41976). EPA did not receive any comments on this proposal; therefore a Responsiveness Summary has not been prepared.

EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of those sites. Any site deleted from the NPL remains eligible for Fund-financed actions in the unlikely event that conditions at the site warrant such action. Section 300.425(e)(3) of the NCP states that Fund-financed actions may be taken at sites deleted from the NPL. Deletion of a site from the NPL does not affect responsible party liability or impede Agency efforts to recover costs associated with response efforts. This partial deletion does not alter the status of all the remaining sites and groundwater plumes of the MMR Site which are not proposed for partial deletion and remain on the NPL.

TABLE 1.—LIST OF SITES FOR PARTIAL DELETION

CS–1 *	CS–12 *	FS–17
CS–1 (CG) *	CS–14 *	FS–18 *
CS–2	CS–15	FS–19
CS–2 (CG) *	CS–16/ CS–17/ DDOU *	FS–20 *
CS–3 *	CS–22	FS–23
CS–3 (CG) *	CY–1 *	FS–25 *
CS–4 *	CY–3	FS–26 (CG)
CS–4 (CG)/ FS–1 (CG) *	FS–2	FS–27
CS–5 *	FS–2 (CG)	LF–1 (CG)
CS–5 (CG) *	FS–3 *	LF–2 (CG)
CS–6 */FS–22	FS–4	LF–3
CS–6 (CG) *	FS–7	LF–3 (CG)
CS–7 *	FS–9 *	LF–4
CS–7 (CG) *	FS–13	LF–5
CS–8/FS–21 *	FS–14	LF–6
CS–8 (CG)	FS–15	SD–2/FS–6/ FS–8
CS–9	FS–16 *	SD–3/FTA–3/ CY–4
CS–11 *		

Key:
CS = Chemical Spill.
CY = Coal Yard.

DDOU = Drum Disposal Operable Unit.
FS = Fuel Spill.
FTA = Fire Training Area.
LF = Landfill.
SD = Storm Drain.
G = U.S. Coast Guard.
* Includes structure(s) at site.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: September 25, 2007.

Robert W. Varney,

Regional Administrator, EPA New England.

■ For the reasons set forth in the preamble title 40 part 300 of the Code of Federal Regulations is amended as follows.

PART 300—[AMENDED]

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

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR 1987 Comp., p. 193.

Appendix B—[Amended]

■ 2. Table 2 of appendix B to part 300 is amended by removing the entry for ''Otis Air National Guard (USAF), Falmouth'' and adding in its place the entry for ''Otis Air National Guard Base/Camp Edwards'' to read as follows:

Appendix B to Part 300—National Priorities List

TABLE 2.—FEDERAL FACILITIES SECTION

State	Site name	City/County	Notes [a]
*	*	*	*
MA	Otis Air National Guard Base/Camp Edwards	Sandwich, Falmouth, Bourne, Mashpee	P
*	*	*	*

* * * * *

P = Sites with partial deletion(s).

* * * * *

[FR Doc. E7–21098 Filed 10–25–07; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3835–F2]

Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correcting amendment.

SUMMARY: On March 30, 2007, we published a final rule entitled ''Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants.'' The effective date was June 28, 2007. This correcting amendment corrects a technical error identified in the March 30, 2007 final rule.

DATES: *Effective Date:* This correcting amendment is effective October 26, 2007.

FOR FURTHER INFORMATION CONTACT: Jeannie Miller, (410) 786–3164.

SUPPLEMENTARY INFORMATION:

I. Background

FR Doc. 07–1435 of March 30, 2007 (72 FR 15198) contained a technical error that this rule serves to identify and correct. In amending subpart E of part 482, we inadvertently omitted existing §§ 482.60, 482.61, 482.62, and 482.66. Our intention was to retain these sections, which address psychiatric hospitals and ''swing-bed'' hospitals, without change.

II. Summary of Errors in the Regulations Text

In amending subpart E of part 482, we inadvertently omitted existing §§ 482.60, 482.61, 482.62, and 482.66. Our intention was to retain these sections, which address psychiatric hospitals and ''swing-bed'' hospitals, without change.

III. Waiver of Proposed Rulemaking and Delayed Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a notice such as this take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). We also ordinarily provide a 30-day delay in the effective date of the provisions of a rule in accordance with section 553(d) of the APA (5 U.S.C. 553(d)). However, we can waive both the notice and comment procedure and the 30-day delay in effective date if the Secretary finds, for good cause, that a notice and comment process and a 30-day delay in effective date are impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice.

We find for good cause that it is unnecessary to undertake notice and comment rulemaking because this final rule merely provides technical corrections to the regulations. We are not making any changes to our existing regulations, but reinstating provisions that have previously been approved and were unintentionally omitted from the final rule that appeared in the March 30, 2007 **Federal Register** (72 FR 15198). Therefore, we believe that undertaking further notice and comment procedures to incorporate these corrections into the update notice is unnecessary and contrary to the public interest.

Further, we believe a delayed effective date is unnecessary because this correcting amendment merely reinstates provisions already approved and in effect. Therefore, we find good cause to waive notice and comment procedures, as well as the 30-day delay in effective date.

List of Subjects in 42 CFR Part 482

Grant programs—health, Hospitals, Medicare, Reporting and recordkeeping requirements.

■ Accordingly, 42 CFR chapter IV is corrected by making the following correcting amendments to part 482.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 2. Subpart E—Requirements for Specialty Hospitals is amended by adding §§ 482.60, 482.61, 482.62, and 482.66, to read as follows:

Subpart E—Requirements for Specialty Hospitals

* * * * *

Sec.

482.60 Special provisions applying to psychiatric hospitals.
482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.
482.62 Condition of participation: Special staff requirements for psychiatric hospitals.
482.66 Special requirements for hospital providers of long-term care services (''swing-beds'').

* * * * *

Subpart E—Requirements for Specialty Hospitals

§ 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospital must—

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

(b) Meet the conditions of participation specified in §§ 482.1 through 482.23 and §§ 482.25 through 482.57;

(c) Maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in § 482.61; and

(d) Meet the staffing requirements specified in § 482.62.

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) *Standard: Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

(1) The identification data must include the patient's legal status.

(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(b) *Standard: Psychiatric evaluation.* Each patient must receive a psychiatric evaluation that must—

(1) Be completed within 60 hours of admission;

(2) Include a medical history;

(3) Contain a record of mental status;

(4) Note the onset of illness and the circumstances leading to admission;

(5) Describe attitudes and behavior;

(6) Estimate intellectual functioning, memory functioning, and orientation; and

(7) Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

(c) *Standard: Treatment plan.* (1) Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities.

The written plan must include—

(i) A substantiated diagnosis;

(ii) Short-term and long-range goals;

(iii) The specific treatment modalities utilized;

(iv) The responsibilities of each member of the treatment team; and

(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) *Standard: Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in § 482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(e) *Standard: Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

§ 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(a) *Standard: Personnel.* The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

(1) Evaluate patients;

(2) Formulate written individualized, comprehensive treatment plans;

(3) Provide active treatment measures; and

(4) Engage in discharge planning.

(b) *Standard: Director of inpatient psychiatric services; medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(1) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(c) *Standard: Availability of medical personnel.* Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are

not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

(d) *Standard: Nursing services.* The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(2) The staffing pattern must insure the availability of a registered professional nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

(e) *Standard: Psychological services.* The hospital must provide or have available psychological services to meet the needs of the patients.

(f) *Standard: Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a masters degree in social work, at least one staff member must have this qualification.

(2) Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate, information with sources outside the hospital.

(g) *Standard: Therapeutic activities.* The hospital must provide a therapeutic activities program.

(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

§ 482.66 Special requirements for hospital providers of long-term care services (''swing-beds'').

A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in § 409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in § 413.114 of this chapter:

(a) *Eligibility.* A hospital must meet the following eligibility requirements:

(1) The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see § 413.24(d)(5) of this chapter).

(2) The hospital is located in a rural area. This includes all areas not delineated as ''urbanized'' areas by the Census Bureau, based on the most recent census.

(3) The hospital does not have in effect a 24-hour nursing waiver granted under § 488.54(c) of this chapter.

(4) The hospital has not had a swing-bed approval terminated within the two years previous to application.

(b) *Skilled nursing facility services.* The facility is substantially in compliance with the following skilled nursing facility requirements contained in subpart B of part 483 of this chapter.

(1) Resident rights (§ 483.10 (b)(3), (b)(4), (b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m)).

(2) Admission, transfer, and discharge rights (§ 483.12 (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7)).

(3) Resident behavior and facility practices (§ 483.13).

(4) Patient activities (§ 483.15(f)).

(5) Social services (§ 483.15(g)).

(6) Discharge planning (§ 483.20(e)).

(7) Specialized rehabilitative services (§ 483.45).

(8) Dental services (§ 483.55).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 22, 2007.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. E7–21213 Filed 10–25–07; 8:45 am]

BILLING CODE 4120–01–P

Proposed Rules

Federal Register
Vol. 72, No. 207
Friday, October 26, 2007

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. 03–002–5]

RIN 0579–AC55

Importation of Nursery Stock; Postentry Quarantine Requirements for Potential Hosts of Chrysanthemum White Rust and Definition of From

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would amend the regulations on importing nursery stock by providing a new option for the postentry quarantine growing period for articles of *Chrysanthemum* spp., *Leucanthemella serotina*, and *Nipponanthemum nipponicum* and amending the definition of *from*. This action will allow interested persons additional time to prepare and submit comments.

DATES: We will consider all comments that we receive on or before November 26, 2007.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*, select ''Animal and Plant Health Inspection Service'' from the agency drop-down menu, then click ''Submit.'' In the Docket ID column, select APHIS–2005–0081 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. 03–002–4, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–002–4.

Reading Room: You may read any comments that we receive on Docket No. 03–002–4 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.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Arnold T. Tschanz, Senior Import Specialist, Commodity Import Analysis and Operations, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 734–5306.

SUPPLEMENTARY INFORMATION: On August 8, 2007, we published in the **Federal Register** (72 FR 44425–44433, Docket No. 03–002–4) a proposed rule that would amend the regulations on importing nursery stock by providing an option in which the postentry quarantine growing period for articles of *Chrysanthemum* spp., *Leucanthemella serotina*, and *Nipponanthemum nipponicum* that are imported from certain locations would be reduced from 6 months to 2 months, provided that the grower of those plants has implemented a systems approach to prevent the imported articles from being infected with chrysanthemum white rust. The proposed rule would also amend the definition of *from.*

Comments on the proposed rule were required to be received on or before October 9, 2007. We are reopening the comment period on Docket No. 03–002–4 until November 26, 2007. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between October 9, 2007, and the date of this notice.

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of October 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–21136 Filed 10–25–07; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–28956; Directorate Identifier 2007–CE–068–AD]

RIN 2120–AA64

Airworthiness Directives; Cessna Aircraft Company Models 525, 525A, and 525B Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Cessna Aircraft Company (Cessna) Models 525, 525A, and 525B airplanes. This proposed AD would require you to inspect the lower wing skin structure, forward wing spar, lower fuselage skin, fairings, and the external fairing frames for corrosion; repair any damage found; apply a corrosion inhibitive sealant to the fuselage fairings before reinstalling; and disable the cockpit mounted pilot relief tube. This proposed AD results from leaking of the cockpit mounted pilot relief tube, which caused corrosion of the airplane structure. We are proposing this AD to detect and correct any damage from corrosion of the airplane structure. Corrosion of the airplane structure could cause structural degradation and lead to structural failure of the airplane with consequent loss of control.

DATES: We must receive comments on this proposed AD by December 26, 2007.

ADDRESSES: Use one of the following addresses to comment on this proposed AD:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.

• *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

• *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Cessna Aircraft Company, Citation Marketing Division, P.O. 7706, Wichita, Kansas 67277; telephone: 1–800–835–4090; fax: 1–800–517–8500.

FOR FURTHER INFORMATION CONTACT: T.N. Baktha, Aerospace Engineer, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: (316) 946–4155; fax: (316) 946–4107.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments regarding this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number, ''FAA–2007–28956; Directorate Identifier 2007–CE–068–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive concerning this proposed AD.

Discussion

Cessna reported wing skin corrosion in a Model 525 and belly skin corrosion in several Model 525A airplanes. Cessna received information on more than 18 cases of significant corrosion. Cessna also received information on 42 cases of some corrosion on Models 525, 525A, and 525B airplanes. Corrosive fluids leaked after use of the cockpit mounted pilot relief tube and caused corrosion of the fuselage skins, fairings, fairing support structure, and wing structure.

This condition, if not corrected, could result in structural degradation and lead to structural failure of the airplane with consequent loss of control.

Relevant Service Information

We have reviewed the following Cessna service information for this AD:

• Service Bulletin SB525–53–20, dated April 30, 2007;

• Service Bulletin SB525A–53–01, dated April 30, 2007;

• Service Bulletin SB525B–53–01, dated April 30, 2007;

• Alert Service Letter ASL525–53–04, Revision 2, dated August 19, 2007;

• Alert Service Letter ASL525A–53–05, Revision 2, dated July 25, 2007; and

• Alert Service Letter ASL525B–53–02, Revision 2, dated July 25, 2007.

The service information describes procedures for the following actions:

• Inspecting the lower wing skin structure, forward wing spars, lower fuselage skin, fairings, and external fairing frames for corrosion;

• Repairing corrosion by blending within specified limits or by contacting the manufacturer to obtain an FAA-approved repair scheme if corrosion damage can not be repaired within the limits specified;

• Doing a surface eddy current inspection or a dye-penetrant inspection on the repaired blended areas for cracks, and contacting the manufacturer to obtain an FAA-approved repair scheme if cracks are found;

• Applying a corrosion inhibitive sealant to the fuselage fairings before reinstalling; and

• Disabling the cockpit mounted relief tube.

FAA's Determination and Requirements of the Proposed AD

We are proposing this AD because we evaluated all information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design. This proposed AD would require you to inspect the lower wing skin structure, forward wing spar, lower fuselage skin, fairings, and the external fairing frames for corrosion; repair any damage found; apply a corrosion inhibitive sealant to the fuselage fairings before reinstalling; and disable the cockpit mounted pilot relief tube.

Costs of Compliance

We estimate that this proposed AD would affect 261 airplanes in the U.S. registry.

We estimate the following costs to do the proposed inspection:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
80 work-hours × $80 per hour = $6,400	Not Applicable	$6,400	$1,670,400

We have no way of determining the number of airplanes that may need repair or further inspection based on the results of the proposed inspection, or the costs associated with such repair or inspection.

We estimate the following costs to do the proposed disabling of the cockpit mounted pilot relief tube:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
.5 work-hours × $80 per hour = $40	Not Applicable	$40	$10,440

Cessna will provide warranty credit to the extent specified in Cessna Citation Service Bulletin SB525–53–20, dated April 30, 2007; Service Bulletin SB525A–53–01, dated April 30, 2007; Service Bulletin SB525B–53–01, dated April 30, 2007; Alert Service Letter ASL525–53–04, Revision 2, dated August 19, 2007; Alert Service Letter ASL525A–53–05, Revision 2, dated July 25, 2007; and Alert Service Letter ASL525B–53–02, Revision 2, dated July 25, 2007.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that

section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket that contains the proposed AD, the regulatory evaluation, any comments received, and other information on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone (800) 647–5527) is located at the street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Cessna Aircraft Company: Docket No. FAA–2007–28956; Directorate Identifier 2007–CE–068–AD.

Comments Due Date

(a) We must receive comments on this airworthiness directive (AD) action by December 26, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to the following airplane models and serial numbers that have a cockpit mounted pilot relief tube installed and are certificated in any category:

Models	Serial Nos.
(1) 525	0001 through 0637.
(2) 525A	0001 through 0347.
(3) 525B	0001 through 0152.

Unsafe Condition

(d) This AD results from leaking of the pilot relief tube, which caused corrosion of the airplane structure. We are issuing this AD to detect and correct any damage from corrosion on the airplane structure. Corrosion of the airplane structure could cause structural degradation and lead to structural failure of the airplane with consequent loss of control.

Compliance

(e) To address this problem, you must do the following, unless already done:

Actions	Compliance	Procedures
(1) Inspect the lower wing skin structure, forward wing spars, lower fuselage skin, fairings, and external fairing frames for corrosion.	Within the next 90 days after the effective date of this AD.	Follow Cessna Citation Alert Service Letter ASL525–53–04, Revision 2, dated August 19, 2007; Alert Service Letter ASL525A–53–05, Revision 2, dated July 25, 2007; or Alert Service Letter ASL525B–53–02, Revision 2, dated July 25, 2007.
(2) If corrosion damage is found in the lower wing skin structure, forward wing spars, lower fuselage skin, fairings, and external fairing frames during the inspection required in paragraph (e)(1) of this AD, repair as specified in the applicable service information. If the corrosion damage can not be repaired within the limits specified in the applicable service information, contact the manufacturer at 1–800–835–4090 for an FAA-approved repair scheme and incorporate this repair.	Before further flight after the inspection required in paragraph (e)(1) of this AD.	Follow Cessna Citation Alert Service Letter ASL525–53–04, Revision 2, dated August 19, 2007; Alert Service Letter ASL525A–53–05, Revision 2, dated July 25, 2007; or Alert Service Letter ASL525B–53–02, Revision 2, dated July 25, 2007.
(3) If corrosion on the lower wing skin structure, forward wing spars, and lower fuselage skin was repaired by blending within the limits specified in the service information, do a surface eddy current inspection or a dye-penetrant inspection for cracks.	Before further flight after the repair by blending was done as specified in paragraph (e)(2) of this AD.	Follow Cessna Citation Alert Service Letter ASL525–53–04, Revision 2, dated August 19, 2007; Alert Service Letter ASL525A–53–05, Revision 2, dated July 25, 2007; or Alert Service Letter ASL525B–53–02, Revision 2, dated July 25, 2007.
(4) If cracks are found during the surface eddy current inspection or the dye-penetrant inspection required in paragraph (e)(3) of this AD, contact the manufacturer for an FAA-approved repair scheme and incorporate this repair.	Before further flight after the inspection required in paragraph (e)(3) of this AD.	Contact Cessna Aircraft Company, Citation Customer Support at 1–800–835–4090.

Actions	Compliance	Procedures
(5) Install the fuselage fairings and apply corrosion inhibitive sealant.	Before further flight after the inspection required in paragraph (e)(1) of this AD if no corrosion was found; or before further flight after doing the repairs and inspections required in paragraphs (e)(2), (e)(3), and (e)(4) of this AD if corrosion or cracks were found.	Follow Cessna Citation Alert Service Letter ASL525–53–04, Revision 2, dated August 19, 2007; Alert Service Letter ASL525A–53–05, Revision 2, dated July 25, 2007; or Alert Service Letter ASL525B–53–02, Revision 2, dated July 25, 2007.
(6) Determine the type of installation of the cockpit mounted pilot relief tube and disable the relief tube.	Within the next 90 days after the effective date of this AD.	Cessna Citation Service Bulletin SB525–53–20, dated April 30, 2007; Service Bulletin SB525A–53–01, dated April 30, 2007; or Service Bulletin SB525B–53–01, dated April 30, 2007.

Alternative Methods of Compliance (AMOCs)

(f) The Manager, Wichita Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: T.N. Baktha, Wichita ACO, Aerospace Engineer, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: (316) 946–4155; fax: (316) 946–4107. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Related Information

(g) To get copies of the service information referenced in this AD, contact Cessna Aircraft Company, Citation Marketing Division, P.O. 7706, Wichita, Kansas 67277; telephone: 1–800–835–4090; fax: 1–800–517–8500. To view the AD docket, go to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, or on the Internet at *http://www.regulations.gov.* The docket number is Docket No. FAA–2007–28956; Directorate Identifier 2007–CE–068–AD.

Issued in Kansas City, Missouri, on October 22, 2007.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–21127 Filed 10–25–07; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2007–0631; FRL–8486–5]

Approval and Promulgation of Implementation Plans; Michigan; Recordkeeping and Reporting Requirements for Abnormal Conditions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve, as part of the Michigan State Implementation Plan (SIP), Michigan's June 29, 2007, request to revise recordkeeping and reporting requirements for abnormal conditions, start-up, shutdown, and malfunction of a source, process, or process equipment. The revised rule contains more specific and complete recordkeeping and reporting requirements than are currently approved into the SIP.

DATES: Comments must be received on or before November 26, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2007–0631, by one of the following methods:

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

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–1767, *dagostino.kathleen@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: October 10, 2007.

Walter W. Kovalick, Jr.,

Acting Regional Administrator, Region 5.

[FR Doc. E7–20944 Filed 10–25–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2007–0192; FRL–8486–7]

Approval and Promulgation of Air Quality Implementation Plans; Michigan; Consumer Products Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is approving a request submitted by the Michigan Department of Environmental Quality (MDEQ) on February 13, 2007, to revise the Michigan State Implementation Plan (SIP). The state has requested approval of two rules in two areas of Part 6, Emission Limitations and Prohibitions—Existing Sources of Volatile Organic Compound (VOC) Emissions by adding R 336.1660, Standards for VOC Emissions from Consumer Products, by adopting by reference the Ozone Transport Commission's Model Rule with some modifications and R 336.1661, Definitions for Consumer Products, to define VOC.

DATES: Comments must be received on or before November 26, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2007–0192, by one of the following methods:

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

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Douglas Aburano, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–6960, *aburano.douglas@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: October 11, 2007.

Walter W. Kovalick, Jr.,

Acting Regional Administrator, Region 5.

[FR Doc. E7–20947 Filed 10–25–07; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 070906497–7584–01]

RIN 0648–AW03

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; For-Hire Fishery off the Southern Atlantic States; Control Date

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

ACTION: Advanced notice of proposed rulemaking; request for comments.

SUMMARY: NMFS announces that it is considering, and is seeking public comment on proposed rulemaking to control future access to the South Atlantic for-hire fishery. If a management regime is developed and implemented under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the control date would limit the number of participants in the fishery. This announcement is intended, in part, to promote awareness of the potential eligibility criteria for future access so as to discourage speculative entry into the fishery while the South Atlantic Fishery Management Council (Council) and NMFS consider whether and how access to the for-hire fishery should be controlled.

DATES: Written comments must be received on or before 5 p.m., local time, November 26, 2007.

ADDRESSES: You may submit comments, identified by 0648–AW03, by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov* by clicking on ''Search For Dockets'' at the top of the screen, then enter the following identifier: 0648–AW03 in the ''RIN'' field and click the ''Submit'' button.
- Fax: Attn: Kate Michie 727–824–5308.
- Mail: Kate Michie, NMFS Southeast Regional Office, Sustainable Fisheries Division, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, South Atlantic Fishery Management Council; toll free 1–866–SAFMC–10 or 843–571–4366; *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: At the June 2007 Council meeting, the Council recommended a control date of March 8, 2007, applicable to persons who are contemplating entering any for-hire fishery (charter and headboats) in the exclusive economic zone (EEZ) of the South Atlantic region. The Council requested that this control date be published in the **Federal Register** to notify fishermen that if they enter such a fishery after March 8, 2007, they may not be assured of future access if the Council and/or NMFS decide to limit entry or impose other measures to manage these fisheries.

Establishment of the control date responds to the Council's concerns that for-hire fisheries are expanding quite rapidly and the perception that many of

those new entrants lack experience and professional expertise in the subject fishery.

Control dates are intended to discourage speculative entry into a fishery, as new entrants entering the fishery after the control date are forewarned that they are not guaranteed future participation in the fishery.

Establishment of this control date does not commit the Council or NMFS to any particular management regime or criteria for entry into the for-hire fishery. Fishermen are not guaranteed future participation in the fishery regardless of their level of participation before or after the control date. The Council may recommend a different control date or it may recommend a management regime that does not involve a control date. Other criteria, such as documentation of landings or fishing effort, may be used to determine eligibility for participation in a limited access fishery. The Council and/or NMFS also may choose to take no further action to control entry or access to the fisheries, in which case the control date may be rescinded. Any action by the Council will be taken pursuant to the requirements for fishery management plan and amendment development established under the Magnuson-Stevens Act.

This notification also gives the public notice that interested participants should locate and preserve records that substantiate and verify their participation in any for-hire fishery in the South Atlantic EEZ.

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

Dated: October 22, 2007.

Samuel D. Rauch III,

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

[FR Doc. E7–21099 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 72, No. 207
Friday, October 26, 2007

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Office of the Chief Economist, USDA.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces that the Department of Agriculture, Office of the Chief Economist, is hereby requesting an extension of a currently approved information collection, Guidelines for Designating Biobased Products for Federal Procurement.

DATES: Comments received by December 26, 2007 will be considered.

Additional Information or Comments: Comments and questions should be directed to Marvin Duncan, USDA, Office of the Chief Economist, Office of Energy Policy and New Uses, Room 4059, South Building, 1400 Independence Avenue, SW., MS–3815, Washington, DC 20250–3815.

SUPPLEMENTARY INFORMATION:

Title: Guidelines for Designating Biobased Products for Federal Procurement.

OMB Control Number: 0503–0011.

Type of Request: Extension of a currently approved information collection.

Abstract: The USDA BioPreferred Program provides that qualifying biobased products that fall under items (generic groups of biobased products) that have been designated for preferred procurement by rule making are required to be purchased by Federal agencies in lieu of their fossil energy-based counterparts, with certain limited exceptions. Further, USDA is required by section 9002 of the Farm Security and Rural Investment Act of 2002 to provide certain information on qualified biobased products to Federal agencies. To meet these statutory requirements, USDA will use a number of forms to gather that information from manufacturers and vendors of biobased products. To the extent feasible, the information sought by USDA can be transmitted electronically using the Web site *http://www.usda.gov/biopreferred.* If electronic transmission of information is not practical, USDA will provide technical assistance to support the transmission of information to USDA. The information collected will enable USDA to meet statutory information requirements that then permit USDA to designate items for preferred procurement under the BioPreferred Program. Once items are designated, manufacturers and vendors of qualifying biobased products that fall under these designated items will benefit from preferred procurement by Federal agencies.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 14.9 hours per response.

Respondents: Manufacturers and vendors of biobased products.

Estimated Number of Respondents: 2,905

Estimated Number of Responses per Respondent: One per manufacturer or vendor.

Estimated Total Annual Burden on Respondents: 14,387 hours one time only. Manufacturers and vendors are asked to respond only once. Therefore, there is no ongoing annual paperwork burden on respondents.

Comments are invited on: (1) 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; (2) 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; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Roger Conway,

Director, Office of Energy Policy and New Uses, U.S. Department of Agriculture.

[FR Doc. E7–21148 Filed 10–25–07; 8:45 am]

BILLING CODE 3410–GO–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Revision to Notice of Proposed Additions

The Committee is making a revision to the Procurement List Proposed Additions published on June 15, 2007 (72 FR 33200). The proposed NPA for the Maintenance Record Holder NSN 8105–00–190–9824 has changed from Bestwork Industries for the Blind, Inc., Runnemede, NJ, to Raleigh Lions Clinic for the Blind, Inc., Raleigh, NC.

The Procurement List Proposed Additions notice citing Bestwork Industries for the Blind, Inc., Runnemede, NJ, is no longer under consideration.

Kimberly M. Zeich,

Director, Program Operations.

[FR Doc. E7–21169 Filed 10–25–07; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List products to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete products and a service previously furnished by such agencies.

Comments Must Be Received on or Before: November 25, 2007.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

For Further Information or to Submit Comments Contact: Kimberly M. Zeich,

Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@jwod.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice for each product will be required to procure the products listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following products are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

Hat Liners, Hoods & Booties

NSN: 8415–LL–DM1–0027—Cotton Knit Winter Liner.
NSN: 8415–LL–DM1–0076—Cloth Hood.
NSN: 8415–LL–DM1–0077—Cotton Canvas Overshoes.
NPA: Community Workshops, Inc., Boston, MA.
Coverage: C-List for the requirements of the Portsmouth Naval Shipyard, Portsmouth, NH.
Contracting Activity: Department of the Navy, Fleet Industrial Supply Center (FISC) Norfolk, Portsmouth Naval Shipyard, Portsmouth, NH.

Maintenance Record Holder

NSN: 8105–00–190–9824—Maintenance Record Holder.
NPA: Raleigh Lions Clinic for the Blind, Inc., Raleigh, NC.
Coverage: B-List for the broad Government requirements as specified by the General Services Administration.
Contracting Activity: General Services Administration, Region 2, Office Supply & Paper Products Acquisition Ctr, New York, NY.

Deletions

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action may result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. If approved, the action may result in authorizing small entities to furnish the products and service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and service proposed for deletion from the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following products and service are proposed for deletion from the Procurement List:

Products

Cup, Disposable

NSN: 7350–00–761–7467—Cup, Disposable, 6 oz.
NSN: 7350–00–914–5088—Cup, Disposable, 10 oz.
NSN: 7350–00–914–5089—Cup, Disposable, 8 oz.

Cup, Disposable (Foam Plastic)

NSN: 7350–00–082–5741—Cup, Disposable (Foam Plastic), 8 oz.
NSN: 7350–00–145–6126—Cup, Disposable (Foam Plastic), 16 oz.
NSN: 7350–00–721–9003—Cup, Disposable (Foam Plastic), 6 oz.
NSN: 7350–00–926–1661—Cup, Disposable (Foam Plastic), 10 oz.

Lid, Plastic (Foam Cup)

NSN: 7350–01–485–7092—Lid, Plastic (Foam Cup), 6 oz.
NSN: 7350–01–485–7093—Lid, Plastic (Foam Cup), 10 oz.
NSN: 7350–01–485–7094—Lid, Plastic (Foam Cup), 8 oz.
NSN: 7350–01–485–7889—Lid, Plastic (Foam Cup), 16 oz.
NPA: The Oklahoma League for the Blind, Oklahoma City, OK.
Contracting Activity: General Services Administration, Southwest Supply Center, Fort Worth, TX.

Cup, Drinking, Styrofoam

NSN: M.R. 537—Cup, Drinking, Styrofoam, 8 oz., 51 ct.
NSN: M.R. 539—Cup, Drinking, Styrofoam, 16 oz., 18 ct.
NPA: The Oklahoma League for the Blind, Oklahoma City, OK.
Contracting Activity: Defense Commissary Agency (DeCA), Fort Lee, VA.

Towel, Machinery Wiping

NSN: 7920–01–448–7003.
NPA: East Texas Lighthouse for the Blind, Tyler, TX.
Contracting Activity: General Services Administration, Southwest Supply Center, Fort Worth, TX.

Protector and Sleeve Transparencies

NSN: 7510–01–483–9754—Transparency Protector, Flip-Frame with Pre-View.
NSN: 7510–01–484–0016—Sleeve, Transparency.
NSN: 7510–01–484–0019—Transparency Protector, Flip-Frame.

Transparency, Ink Jet

NSN: 7530–01–484–1753.
NPA: Industries of the Blind, Inc., Greensboro, NC.
Contracting Activity: General Services Administration, Office Supplies & Paper Products Acquisition Ctr, New York, NY.

Service

Service Type/Location: Janitorial/Custodial, U.S. Department of Agriculture, Animal and Plant Health Inspection Service/PPQ, Asian Longhorn Beetle Project, 3920 N. Rockwell, Chicago, IL.
NPA: Habilitative Systems, Inc., Chicago, IL.
Contracting Activity: U.S. Department of Agriculture, Animal & Plant Health Inspection Service, Minneapolis, MN.

Kimberly M. Zeich,

Director, Program Operations.

[FR Doc. E7–21170 Filed 10–25–07; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Addition to the Procurement List.

SUMMARY: This action adds to the Procurement List a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* November 25, 2007.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Kimberly M. Zeich, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@jwod.gov.*

SUPPLEMENTARY INFORMATION: On August 31, 2007, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (72 FR 50323) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the service and impact of the addition on the current or most recent contractors, the Committee has determined that the service listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the service to the Government.

2. The action will result in authorizing small entities to furnish the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the service proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service is added to the Procurement List:

Service

Service Type/Location: Custodial Services, Roanoke Regional Airport, Transportation Security Administration, (Break-room, hallway, office & private restroom), 5202 Aviation Drive, NW., Roanoke, VA.

NPA: Goodwill Industries of the Valleys, Inc., Roanoke, VA.

Contracting Activity: General Service Administration, Region 3, Philadelphia, PA.

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Kimberly M. Zeich,

Director, Program Operations.

[FR Doc. E7–21171 Filed 10–25–07; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Correction of Notice of Additions and Deletion

In the document appearing on page 56984, FR Doc E7–19717, Procurement List Additions and Deletions, on October 5, 2007, the Committee published the following product and NSNs (Long Format Replacement Pages—FCCL 7510–00–NSH–0257; 7510–01–537–1400) with coverage as A-List for the total Government requirement as specified by the General Services Administration.

This notice corrects the coverage for the above mentioned product and NSNs to B-List for the Broad Government requirement as specified by the General Services Administration.

Kimberly M. Zeich,

Director, Program Operations.

[FR Doc. E7–21172 Filed 10–25–07; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–801, A–475–801]

Ball Bearings and Parts Thereof from France and Italy: Rescission of Antidumping Duty Changed–Circumstances Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On March 2, 2007, in response to a request from an interested party, the Department of Commerce initiated a changed–circumstances review of the antidumping duty order on ball bearings and parts thereof from France. On March 9, 2007, the Department self–initiated changed–circumstances reviews of the antidumping duty orders on ball bearings and parts thereof from Italy and the United Kingdom. We are now rescinding the changed–circumstances reviews for France and Italy because we have initiated administrative reviews covering the firms in question and intend to address any considerations arising from the changed–circumstances reviews on the orders on ball bearings and parts thereof from France and Italy in the context of the 2006/2007 administrative review of these orders.

EFFECTIVE DATE: October 26, 2007.

FOR FURTHER INFORMATION CONTACT: Kristin Case or Edythe Artman, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–3174 or (202) 482–3931, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department of Commerce (the Department) published antidumping duty orders on ball bearings and parts thereof (ball bearings) from France, Italy, and the United Kingdom on May 15, 1989. See *Antidumping Duty Orders: Ball Bearings, Cylindrical Roller Bearings, Spherical Plain Bearings, and Parts Thereof From France*, 54 FR 20902 (May 15, 1989), *Antidumping Duty Orders: Ball Bearings and Cylindrical Roller Bearings, and Parts Thereof From Italy*; 54 FR 20903 (May 15, 1989), and *Antidumping Duty Orders and Amendments to the Final Determinations of Sales at Less Than Fair Value: Ball Bearings and Cylindrical Roller Bearings, and Parts Thereof From the United Kingdom*, 54 FR 20910 (May 15, 1989).

On August 11, 2000, the Department revoked the antidumping duty order on ball bearings from Italy with respect to those produced by Somecat S.p.A. (SNFA Italy)[1] and the order on ball bearings from France with respect to those produced by Societe Nouvelle de Fabrication Aeronautique S.A.S.U. (SNFA France). See *Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, Germany, Italy, Japan, Romania, Singapore, Sweden, and the United Kingdom; Final Results of Antidumping Duty Administrative Reviews and Revocation of Orders in Part*, 65 FR 49219 (August 11, 2000). On July 12, 2001, the Department revoked the order on ball bearings from the United Kingdom with respect to SNFA Bearings Ltd. (SNFA UK). See *Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts*

[1] The Department had determined previously that Somecat bearings were marked ≥SNFA Italy≥. See Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, Germany, Italy, Japan, Romania, Sweden, and the United Kingdom; Final Results of Antidumping Duty Administrative Reviews, 64 FR 35590 (July 1, 1999), and accompanying Issues and Decision Memorandum at Comment 1 in Section 11.B.

Thereof From France, Germany, Italy, Japan, Sweden, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews and Revocation of Orders in Part, 66 FR 36551 (July 12, 2001).

On January 9, 2007, SKF France S.A. and SKF Aerospace France S.A.S. (collectively SKF France) and SNFA France notified the Department of a change of ownership in SNFA France and requested the initiation of a changed–circumstances review of the order on ball bearings from France. In a separate filing on the same date, SKF Industries S.p.A. (SKF Italy) and SNFA Italy notified the Department of a change in ownership of SNFA Italy. On January 26, 2007, SKF UK Ltd. (SKF UK) and SNFA UK filed such a notification with respect to SNFA UK. Each notification stated that AB SKF, the parent SKF company, had purchased all outstanding shares of the SNFA companies through its subsidiary, SKF Holding France S.A., on July 4, 2006.

We initiated a changed–circumstances review pursuant to the request by SKF France and SNFA France on March 2, 2007. See *Ball Bearings and Parts Thereof from France: Initiation of an Antidumping Duty Changed–Circumstances Review*, 72 FR 9513 (March 2, 2007). On March 9, 2007, the Department self–initiated changed–circumstances reviews of the orders on ball bearings from Italy and the United Kingdom. See *Ball Bearings and Parts Thereof from Italy and the United Kingdom: Initiation of Antidumping Duty Changed–Circumstances Reviews*, 72 FR 10643 (March 9, 2007). For each review, we have requested more detailed information from the merged SKF/SNFA entities. The entities have complied with our requests and Timken US Corporation, the petitioner in the investigations, has submitted comments on the information.

On June 29, 2007, we initiated administrative reviews of the orders on ball bearings from France, Italy, and the United Kingdom for the period from May 1, 2006, through April 30, 2007. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, Request for Revocation in Part and Deferral of Administrative Review, 72 FR 35690 (June 29, 2007). After analysis of the quantity and value of the sales of ball bearings from France during the period of review, we selected SKF France as a respondent for individual examination in the administrative review of the order covering that merchandise. See ''Memorandum to Laurie Parkhill from Thomas Schauer regarding Ball Bearings and Parts Thereof from France Respondent Selection'' dated August 14, 2007. After a similar analysis of sales of ball bearings from Italy, we selected SKF Italy as a respondent for individual examination in the review of the order covering ball bearings from Italy. See ''Memorandum to Laurie Parkhill from Thomas Schauer regarding Ball Bearings and Parts Thereof from Italy Respondent Selection'' dated August 14, 2007. We received no request to review the sales of SKF UK in the administrative review of the order on ball bearings from the United Kingdom.

Scope of the Order

The products covered by these orders are ball bearings and parts thereof. These products include all bearings that employ balls as the rolling element. Imports of these products are classified under the following categories: antifriction balls, ball bearings with integral shafts, ball bearings (including radial ball bearings) and parts thereof, and housed or mounted ball bearing units and parts thereof.

Imports of these products are classified under the following *Harmonized Tariff Schedules of the United States* (HTSUS) subheadings: 3926.90.45, 4016.93.00, 4016.93.10, 4016.93.50, 6909.19.5010, 8431.20.00, 8431.39.0010, 8482.10.10, 8482.10.50, 8482.80.00, 8482.91.00, 8482.99.05, 8482.99.2580, 8482.99.35, 8482.99.6595, 8483.20.40, 8483.20.80, 8483.50.8040, 8483.50.90, 8483.90.20, 8483.90.30, 8483.90.70, 8708.50.50, 8708.60.50, 8708.60.80, 8708.70.6060, 8708.70.8050, 8708.93.30, 8708.93.5000, 8708.93.6000, 8708.93.75, 8708.99.06, 8708.99.31, 8708.99.4960, 8708.99.50, 8708.99.5800, 8708.99.8080, 8803.10.00, 8803.20.00, 8803.30.00, 8803.90.30, and 8803.90.90.

As a result of recent changes to the Harmonized Tariff Schedule, effective February 2, 2007, the subject merchandise is also classifiable under the following additional HTS item numbers: 8708.30.5090, 8708.40.7500, 8708.50.7900, 8708.50.8900, 8708.50.9150, 8708.50.9900, 8708.80.6590, 8708.94.75, 8708.95.2000, 8708.99.5500, 8708.99.68, and 8708.99.8180.

Although the HTSUS item numbers above are provided for convenience and customs purposes, written descriptions of the scope of these orders remain dispositive.

For a listing of scope determinations which pertain to the orders, see the Scope Determination Memorandum from the Antifriction Bearings Team to Laurie Parkhill, dated May 29, 2007, which is on file in the Central Records Unit (CRU) of the main Commerce building, room B–099, in the General Issues record (A–100–001) for the 2005–2006 reviews.

Rescission of Reviews

The mergers of the SKF/SNFA entities in France, Italy, and the United Kingdom occurred in July 2006, during the period under review in the 2006/2007 administrative reviews of the orders on ball bearings from those countries. Because SKF France and SKF Italy have been selected as respondents for individual examination in those reviews, we will be examining the impact of the mergers with respect to the sales that they, or their subsidiaries, made to the United States during the period of review and the effect that these mergers have had on the operations and management of the relevant firms for the purposes of determining, among other things, whether the SKF companies should be collapsed with their SNFA counterparts. Thus, we intend to address any considerations arising from the changed–circumstances reviews on ball bearings from France and Italy in the context of the administrative reviews for SKF France and SKF Italy. Accordingly, we are rescinding the changed–circumstances reviews with respect to the antidumping duty orders on ball bearings and parts thereof from France and Italy.

We will incorporate the records of the rescinded reviews into the records of the appropriate administrative reviews.

Dated: October 19, 2007.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E7–21118 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–816]

Corrosion–Resistant Carbon Steel Flat Products From Korea: Extension of Time Limits for the Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Victoria Cho at (202) 482–5075, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On September 29, 2006, the U.S. Department of Commerce (''Department'') published a notice of initiation of the administrative review of the antidumping duty order on corrosion–resistant carbon steel flat products from Korea, covering the period August 1, 2005 to July 31, 2006. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 71 FR 57465 (September 29, 2006). On September 10, 2007, the Department published the preliminary results of this review. *See Certain Corrosion Resistant Carbon Steel Flat Products from the Republic of Korea: Notice of Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review*, 72 FR 51584 (September 10, 2007). The final results of this review are currently due no later than January 8, 2008.

Extension of Time Limit of Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), requires the Department to issue final results within 120 days after the date on which the preliminary results are published. However, if it is not practicable to complete the review within that time period, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the final results to a maximum of 180 days. *See also* 19 CFR 351.213(h)(2).

We determine that it is not practicable to complete the final results of this review within the original time limit. Several technical issues arose which require the collection and analyses of certain additional information after the preliminary results. Therefore, to allow sufficient time to collect and analyze the additional information, and to conduct the briefing process, the Department is fully extending the final results. The final results are now due not later than March 10, 2008, the next business day after 180 days from publication of the preliminary results. The amended schedule for interested parties to submit case briefs, written comments, and/or hearing is not later than Monday, January 14, 2008. Rebuttal briefs are limited to issues raised in such briefs or comments and may be filed no later than five days after the time limit for filing the case briefs or comments. *See* 19 CFR 351.309(d). Any hearing, if requested, ordinarily will be held two days after the due date of the rebuttal briefs.

This extension is in accordance with section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

Dated: October 22, 2007.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E7–21114 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–838, A–331–802, A–533–840, A–549–822, A–552–802]

Certain Frozen Warmwater Shrimp From Brazil, Ecuador, India, Thailand, and the Socialist Republic of Vietnam: Notice of Extension of Time Limits for the Preliminary Results of the Second Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: October 26, 2007.

FOR FURTHER INFORMATION CONTACT: Kate Johnson (Brazil) at (202) 482–4929, David Goldberger (Ecuador) at (202) 482–4136, Elizabeth Eastwood (India) at (202) 482–3874, Irina Itkin (Thailand) at (202) 482–0656, and Irene Gorelik (Vietnam) at (202) 482–6905, AD/CVD Operations, Offices 2 and 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On April 6, 2007, the Department of Commerce (the Department) published notices of initiation of the administrative reviews of the antidumping duty orders on certain frozen warmwater shrimp from Brazil, Ecuador, India, and Thailand, and the Socialist Republic of Vietnam (Vietnam), covering the period February 1, 2006, through January 31, 2007. *See Notice of Initiation of Administrative Reviews of the Antidumping Duty Orders on Certain Frozen Warmwater Shrimp from Brazil, Ecuador, India, and Thailand*, 72 FR 17100 (April 6, 2007); and *Notice of Initiation of Administrative Reviews of the Antidumping Duty Orders on Frozen Warmwater Shrimp from the Socialist Republic of Vietnam and the People's Republic of China*, 72 FR 17095 (April 6, 2007).

In July 2007, after issuing quantity and value questionnaires and receiving responses, the Department selected mandatory respondents in each of the above–mentioned administrative reviews. *See* the July 17, 2007, Memoranda from James Maeder to Stephen J. Claeys entitled: ''Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from India: Selection of Respondents for Individual Review≥; and ''Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from Thailand: Selection of Respondents for Individual Review≥; the July 18, 2007, Memorandum from James C. Doyle to Stephen J. Claeys entitled: ''Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Selection of Respondents≥; the July 19, 2007, Memoranda from James Maeder to Stephen J. Claeys entitled: ''Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from Brazil: Selection of Respondents for Individual Review≥; and ''Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from Ecuador: Selection of Respondents for Individual Review.''

In August and September 2007, the Department rescinded the Brazil, Ecuador, and Thailand administrative reviews with respect to certain companies. *See Certain Frozen Warmwater Shrimp from Brazil: Partial Rescission of the Antidumping Duty Administrative Review*, 72 FR 48616 (August 24, 2007); *Certain Frozen Warmwater Shrimp from Ecuador: Partial Rescission of the Antidumping Duty Administrative Review*, 72 FR 48616 (August 24, 2007); and *Certain Frozen Warmwater Shrimp from Thailand; Partial Rescission of Antidumping Duty Administrative Review*, 72 FR 50931 (September 5, 2007).

Extension of Time Limit of Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to make a preliminary determination in an administrative review within 245 days after the last day of the anniversary month of an order or finding for which a review is requested. Consistent with section 751(a)(3)(A) of the Act, the Department may extend the 245–day period to 365 days if it is not practicable to complete the review within a 245–day period. The deadline for the preliminary results of these reviews is currently October 31, 2007.

The Department determines that completion of the preliminary results of these administrative reviews within the statutory time period is not practicable.

Due to the additional time needed for respondent selection, the Department was unable to issue its initial antidumping duty questionnaires to the selected companies until July 2007 in each of these administrative reviews. The Department thus requires additional time to conduct its analysis for each company in each of these reviews. Therefore, in accordance with section 751(a)(3)(A) the Act, we are extending the time period for issuing the preliminary results of these reviews by 120 days, until February 28, 2008. The final results continue to be due 120 days after the publication of the preliminary results.

This notice is published pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

Dated: October 22, 2007.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E7–21110 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–841/Brazil]
[A–570–924/People's Republic of China]
[A–549–825/Thailand]
[A–520–803/The United Arab Emirates]

Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Brazil, the People's Republic of China, Thailand, and the United Arab Emirates: Initiation of Antidumping Duty Investigations

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: October 26, 2007.

FOR FURTHER INFORMATION CONTACT: Mike Heaney (Brazil), AD/CVD Operations, Office 7, Erin Begnal (the People's Republic of China) AD/CVD Operations, Office 9, Stephen Bailey (Thailand), AD/CVD Operations, Office 7, Douglas Kirby (the United Arab Emirates), AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–4475, (202) 482–1442, (202) 482–0193, and (202) 482–3782, respectively.

SUPPLEMENTARY INFORMATION:

The Petitions

On September 28, 2007, the Department of Commerce (the Department) received petitions on imports of PET Film from Brazil, the People's Republic of China (PRC), Thailand, and the United Arab Emirates (UAE) (petitions) filed in proper form by Dupont Teijin Films, Mitsubishi Polyester Film Inc., SKC Inc., and Toray Plastics (America) Inc., (collectively, petitioners). *See Antidumping Duty Petition: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Brazil, Republic of China, Thailand, and the United Arab Emirates* (September 28, 2007). On October 3, 2007, the Department issued a request for additional information and clarification of certain areas of the petitions. Based on the Department's request, petitioners filed supplements to the petitions for all countries on October 9, 2007, and October 10, 2007. *See Supplemental Questionnaire Response: Petition for the Imposition of Antidumping Duties: Polyethylene Terephthalate Film, Sheet, and Strip from the United Arab Emirates*. On October 12, 2007, and October 15, 2007, the Department requested further clarifications from petitioners by phone. *See Memorandum to the File: Telephone Call to Petitioners Regarding the Antidumping Petition on Polyethylene Terephthalate Film, Sheet, and Strip from Brazil, the People's Republic of China, Thailand, and the United Arab Emirates, dated* October 12, 2007; *see also Memorandum to the File: Telephone conversation with Petitioners' counsel in connection with the Petitions on Polyethylene Terephthalate Film, Sheet, and Strip from Brazil, the People's Republic of China (the PRC), Thailand, and the United Arab Emirates (the UAE)*, dated October 15, 2007. On October 15, 2007, petitioners submitted additional supplements to the Petitions. *See Second Supplemental Questionnaire Response: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Brazil, the People's Republic of China, Thailand, and the United Arab Emirates*, dated October 15, 2007. On October 15, 2007, Ms. Meredith Rutherford of the Department's Office of Policy, telephoned petitioners to request that they submit relevant pages from the International Trade Commission publication concerning the domestic like product. *See Memorandum to the File: Telephone conversation with Petitioners' counsel in connection with the Petitioners on Polyethylene Terephthalate Film, Sheet, and Strip from Brazil, the People's Republic of China (the PRC), Thailand, and the United Arab Emirates (the UAE)*, dated October 15, 2007. On October 16, 2007, petitioners submitted addendums to their October 15, 2007 supplements. *See Additional Exhibits to the Second Supplemental Questionnaire Response: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Thailand, and the United Arab Emirates*, dated October 16, 2007; *see also Supplement to the Petition Regarding Domestic–Like Product*, dated October 16, 2007. On October 16, 2007, the Department telephoned petitioners requesting further information for Brazil, Thailand, and the UAE to which petitioners submitted responses on October 17, 2007, and October 18, 2007. *See Memorandum to the File: Telephone Call to Petitioners Regarding the Antidumping Petition and October 16, 2007, Supplement to the Petition on Polyethylene Terephthalate Film, Sheet, and Strip from Thailand and the United Arab Emirates*, dated October 17, 2007; *see also Memorandum to the File: Polyethylene Terephthalate Film, Sheet and Strip from Brazil; Telecon with Counsel for Petitioners; Date of Home Market Prices*, dated October 16, 2007; Supplement to the Petition, dated October 17, 2007, at Exhibit 1; and Supplement to the Petition, dated October 18, 2007, at Exhibit 1. On October 17, 2007, the Department telephoned petitioners regarding their responses to our October 16, 2007, inquires for Brazil, Thailand, and the UAE. *See Memorandum to the File: Telephone Call to Petitioners Regarding Submission of Information in the Antidumping Petition on Polyethylene Terephthalate Film, Sheet, and Strip from Thailand, Brazil, and the United Arab Emirates*, dated October 17, 2007. On October 18, 2007, the Department telephoned petitioners requesting additional clarification of its October, 17, 2007, filings for Thailand and the UAE. *See Memorandum to the File: Telephone Call to Petitioners Regarding the Antidumping Petition on Polyethylene Terephthalate Film, Sheet, and Strip from Thailand and the United Arab Emirates*, dated October 18, 2007.

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), petitioners allege that imports of PET Film from Brazil, the PRC, Thailand, and the UAE are being, or are likely to be, sold in the United States at less than fair value, within the meaning of section 731 of the Act, and that such imports materially injure, or threaten material injury to, an industry in the United States.

The Department finds that petitioners filed these petitions on behalf of the domestic industry because petitioners are an interested party as defined in section 771(9)(C) of the Act, and petitioners have demonstrated sufficient industry support with respect to the

investigations that petitioners are requesting the Department to initiate (*see* ''Determination of Industry Support for the Petitions'' below).

Scope of Investigations

The products covered by these investigations are all gauges of raw, pre–treated, or primed PET Film, whether extruded or co–extruded. Excluded are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance–enhancing resinous or inorganic layer more than 0.00001 inches thick. Also excluded is Roller transport cleaning film which has at least one of its surfaces modified by application of 0.5 micrometers of SBR latex. Tracing and drafting film is also excluded. PET Film is classifiable under subheading 3920.62.00.90 of the Harmonized Tariff Schedule of the United States (HTSUS). While HTSUS subheadings are provided for convenience and Customs purposes, our written description of the scope of these investigations is dispositive.

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers who support the petition account for (i) at least 25 percent of the total production of the domestic like product and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers accounting for more than 50 percent of the total production of the domestic like product, the Department shall (i) poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A) or (ii) determine industry support using a statistically valid sampling method if there is a large number of producers in the industry.

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information because the Department determines industry support at the time of initiation. Although this may result in different definitions of the domestic like product, such differences do not render the decision of either agency contrary to law. *See USEC, Inc. v. United States*, 132 F. Supp. 2d 1, 8 (CIT 2001); *see also Algoma Steel Corp. Ltd. v. United States*, 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989), *cert. denied* 492 U.S. 919 (1989).

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like–product analysis begins is ''the article subject to an investigation,'' *i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition.

With regard to the domestic like product, petitioners do not offer a definition of domestic like product distinct from the scope of the investigations. Based on our analysis of the information submitted on the record, we have determined that PET Film constitutes a single domestic like product and we have analyzed industry support in terms of that domestic like product. For a discussion of the domestic like–product analysis in these cases, *see* the *Antidumping Duty Investigation Initiation Checklist: Polyethylene Terephthalate Film, Sheet, and Strip from Brazil* (*Brazil Initiation Checklist*) at Attachment II (Analysis of Industry Support), *Antidumping Duty Investigation Initiation Checklist: Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China (PRC)* (*PRC Initiation Checklist*) at Attachment II (Analysis of Industry Support), *Antidumping Duty Investigation Initiation Checklist: Polyethylene Terephthalate Film, Sheet, and Strip from Thailand (Thailand Initiation Checklist)* at Attachment II (Analysis of Industry Support), and the *Antidumping Duty Investigation Initiation Checklist: Polyethylene Terephthalate Film, Sheet, and Strip from the United Arab Emirates (UAE)* (*UAE Initiation Checklist*) at Attachment II (Analysis of Industry Support), on file in the Central Records Unit, Room B–099 of the main Department of Commerce building.

In determining whether petitioners have standing (*i.e.*, those domestic workers and producers supporting the petition account for (i) at least 25 percent of the total production of the domestic like product and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition), we considered the industry support data contained in the petition with reference to the domestic like product as defined in Attachment I, (Scope of these petitions), to the *Brazil Initiation Checklist*, *PRC Initiation Checklist*, *Thailand Initiation Checklist*, and *UAE Initiation Checklist*. To establish industry support, petitioners provided their production of the domestic like product for the year 2006, and compared that to production of the domestic like product for the industry. For further discussion, see the Brazil Initiation Checklist, PRC Initiation Checklist, Thailand Initiation Checklist, and UAE Initiation Checklist at Attachment II.

Our review of the data provided in these petitions, supplemental submissions, and other information readily available to the Department indicates that petitioners have established industry support. First, these petitions established support from domestic producers accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.*, polling). *See* section 732(c)(4)(D) of the Act. Second, the domestic producers have met the statutory criteria for industry support under section 732(c)(4)(A)(i) because the domestic producers who support these petitions account for at least 25 percent of the total production of the domestic like product. Finally, the domestic producers have met the statutory criteria for industry support under 732(c)(4)(A)(ii) because the domestic producers who support these petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, these petitions. Accordingly, the Department determines that these petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act. *See* the *Brazil Initiation Checklist*, *PRC Initiation Checklist*, *Thailand Initiation*

Checklist, and *UAE Initiation Checklist* at Attachment II.

The Department finds that petitioners filed these petitions on behalf of the domestic industry in accordance with section 732(c)(4)(A) of the Act. Petitioners are an interested party as defined in section 771(9)(C) of the Act and have demonstrated sufficient industry support in favor of the initiation of the antidumping duty investigations. *See Brazil Initiation Checklist*, *PRC Initiation Checklist*, *Thailand Initiation Checklist*, and *UAE Initiation Checklist* at Attachment II.

Allegations and Evidence of Material Injury and Causation

Petitioners allege that the U.S. industry producing the domestic like product is being materially injured by reason of the imports of the subject merchandise sold at less than normal value. While the imports from the UAE do not meet the statutory requirement for cumulation on a volume basis, in its analysis for threat, petitioners allege that imports from the UAE will imminently account for more than three percent of all imports of the subject merchandise by volume and, therefore, they are not negligible. In addition, petitioners have demonstrated that imports from the UAE for the first half of 2007 do meet the statutory requirement for cumulation on a volume basis. *See* section 771(24)(A)(iv) of the Act; *see also Brazil Initiation Checklist*, *PRC Initiation Checklist*, *Thailand Initiation Checklist*, and *UAE Initiation Checklist* at Attachment III. Petitioners contend that the industry's injured condition is illustrated by reduced market share, lost revenue and sales, reduced production and capacity utilization, reduced shipments, underselling and price depressing and suppressing effects, reduced employment, and decline in financial performance. We have assessed the allegations and supporting evidence regarding material injury and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation. *See Brazil Initiation Checklist*, *PRC Initiation Checklist*, *Thailand Initiation Checklist*, and *UAE Initiation Checklist* at Attachment III.

Periods of Investigation

For Brazil, Thailand, and the UAE, in accordance with section 351.204(b) of the Department's regulations, because these petitions were filed on September 28, 2007, the anticipated period of investigation (POI) is July 1, 2006 through June 30, 2007. For the PRC, the anticipated POI is January 1, 2007, through June 30, 2007.

Allegations of Sales at Less Than Fair Value

The following is a description of the allegations of sales at less than fair value upon which the Department has based its decision to initiate investigations with respect to Brazil, the PRC, Thailand, and the UAE. The sources of data for the deductions and adjustments relating to U.S. price and normal value are discussed in greater detail in the *Brazil Initiation Checklist*, *PRC Initiation Checklist*, **Thailand Initiation Checklist**, and **UAE Initiation Checklist**. Should the need arise to use any of this information as facts available under section 776 of the Act, we may reexamine the information and revise the margin calculation, if appropriate.

Alleged U.S. Price and Normal Value: Brazil

Petitioners state that Brazilian producer Terphane Ltda.'s U.S. affiliate, Terphane Inc., was the importer of record for PET Film imports from Brazil during the POI. Petitioners calculated constructed export price (CEP) using information regarding a representative sale of 48–gauge packaging film made through Terphane Inc. to an unaffiliated customer in the United States. Petitioners deducted from U.S. price a mark–up based on the expenses and profit rate of a U.S. importer of PET Film. We adjusted petitioners' mark–up value to exclude certain expenses covered in separate deductions (*i.e.*, inland freight from the U.S. port to the distribution warehouse and brokerage charges). Petitioners also deducted from U.S. price an amount for international freight and insurance, U.S. customs duties, inland freight from the U.S. warehouse to the customer and credit expense. *See Brazil Initiation Checklist*. International freight and insurance were calculated as the difference between the value of PET Film imports from Brazil on a CIF basis, and the value of PET Film imports from Brazil on a custom's value basis as reported on the ITC's ''DataWeb'' *http://usitc.gov/tata/hts/other/dataweb*. In calculating U.S. customs duties, petitioners applied U.S. duty rates to the customs value AUV for import data for the POI. U.S. inland freight was based on the freight expenses of a U.S. producer to the same customer. Petitioners calculated credit using the average U.S. prime rates available for the POI, and used what petitioners describe as the standard thirty-day credit period between shipment and payment for PET Film sales.

Petitioners based normal value on a sale of 48–gauge packaging film by Terphane Ltda. to one of its home market customers in Brazil during the POI. Petitioners deducted credit and packing expenses. Petitioners calculated credit using the standard thirty-day period between shipment and payment dates for PET Film sales consistent with other countries subject to these petitions, and used average prime rates available for Brazil for the POI. Petitioners maintain packing costs in Brazil and the United States are equivalent and therefore based packing expenses on those of one petitioning firm. *See Brazil Initiation Checklist*. Petitioners made no deduction for inland freight in calculating NV, claiming the terms of sale were essentially ex–factory. See Supplement to the Brazil Petition, dated October 16, 2007, at Exhibit 4.

Petitioners also allege Terphane Ltda.'s home market sale is below its cost of production. Petitioners therefore calculated constructed value for 48–gauge packaging film, basing Terphane Ltda.'s cost of production on that of a U.S. producer's experience during the POI, adjusted for known differences between the United States and Brazil. *See* ''Cost of Production and Constructed Value'' section, *infra*.

Alleged U.S. Price and Normal Value: The People's Republic of China

For U.S. price, petitioners relied on price information of a representative sale of Chinese PET Film sold by a U.S. distributor to a U.S. customer in early 2007, based on the experience of a salesperson at one of the petitioning firms. *See* PRC Petition at Exhibit 12; Supplemental Response, dated October 10, 2007, at Exhibit 1 (''October 10, 2007 Supplemental Response''); and Supplemental Response, dated October 15, 2007, at Exhibit 2 (''October 15, 2007 Supplemental Response''). The price information supplied by petitioners was for 48 gauge packaging film, which falls within the scope of these petitions. Petitioners deducted from the price the costs associated with exporting and delivering the product, including a distributor mark–up fee, ocean freight and insurance charges, U.S. duty, port and wharfage fees, and U.S. inland freight. We adjusted petitioners' mark–up value to exclude certain expenses covered in separate deductions (*i.e.*, inland freight and brokerage charges). *See PRC Initiation Checklist* at Attachment V.

Because the Department considers the PRC to be a non–market-economy country (NME), petitioners constructed normal value based on the factors–of-

production methodology pursuant to section 773(c) of the Act. Recently, the Department examined the PRC's market status and determined that NME status should continue for the PRC. *See Memorandum from the Office of Policy to David M. Spooner, Assistant Secretary for Import Administration, Regarding the People's Republic of China Status as a Non–Market Economy*, dated August 30, 2006. (This document is available online at *http://ia.ita.doc.gov/download/prc–nme-status/prc–lined-paper–memo–08302006.pdf*.). In addition, in two recent investigations, the Department also determined that the PRC is an NME country. *See Final Determination of Sales at Less Than Fair Value: Certain Activated Carbon from the People's Republic of China*, 72 FR 9508 (March 2, 2007), and *Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China*, 72 FR 19690 (April 19, 2007). In accordance with section 771(18)(C)(i) of the Act, the NME status remains in effect until revoked by the Department. The presumption of the NME status of the PRC has not been revoked by the Department and, therefore, remains in effect for purposes of the initiation of this investigation. Accordingly, the normal value of the product is based appropriately on factors of production valued in a surrogate market–economy country in accordance with section 773(c) of the Act. During the course of this investigation, all parties will have the opportunity to provide relevant information related to the issues of the PRC's NME status and the granting of separate rates to individual exporters.

Petitioners assert that India is the appropriate surrogate country for valuing the factors of production for the PRC because India is: (1) a significant producer of identical merchandise; and (2) at a level of economic development comparable to that of the PRC. *See* PRC Petition at 41. Based on the information provided by petitioners, we believe that petitioners' use of India as a surrogate country is appropriate for purposes of initiating this investigation. After the initiation of the investigation, we will solicit comments regarding surrogate country selection. Also, pursuant to 19 CFR 351.301(c)(3)(i), interested parties will be provided an opportunity to submit publicly available information to value factors of production within 40 days of the date of publication of the preliminary determination.

Petitioners provided dumping–margin calculations using the Department's NME methodology as required by 19 CFR 351.202(b)(7)(i)(C) and 19 CFR 351.408. Petitioners calculated normal value for the U.S. price discussed above based on U.S. industry experience for producing PET Film, which they state is consistent with standard PET Film production methodology. Petitioners also state that Chinese producers use substantially the same material inputs and production processes as U.S. producers. *See* PRC Petition at 41–42 and Exhibit 15. Petitioners state that the primary materials used to produce PET Film are monoethylene glycol (''MEG''), terephthalic acid (''PTA''), and/or dimethyl terephthalate (''DMT''), although they believe that PRC producers utilize PTA rather than DMT. *See* PRC Petition at 42 and October 10, 2007 Supplemental Response at 7.

For the normal–value calculations, pursuant to section 773(c)(4) of the Act, petitioners used surrogate values from a variety of sources, including the *ASFI Monthly Bulletin*, published by the Association of Synthetic Fibre Industry of India, Indian import statistics from the *World Trade Atlas*, the International Energy Agency's (''IEA'') *Energy Prices & Taxes 2007 (First Quarter)* edition, the Department's NME Wage Rate for the PRC, and publicly available financial statements, to value the factors of production (FOP). *See* PRC Petition at 42–43 and Exhibits 16–20; October 10, 2007 Supplemental Response at Exhibits 5, 6, 7 and 9; and October 15, 2007 Supplemental Response at Exhibit 4. Petitioners converted the inputs valued in Indian rupees to U.S. dollars based on the average rupee/U.S. dollar exchange rate for the POI, as reported on the Department's website at *http://ia.ita.doc.gov/exchange/index.html*.

For PTA and MEG, the main raw materials in the production of PET Film, petitioners provided surrogate values based on the *ASFI Monthly Bulletin* from 2006, inflated to the POI using a Wholesale Price Index (''WPI'') inflator. *See* PRC Petition at 42 and Exhibit 16 and October 15, 2007 Supplemental Response at Exhibit 4. In addition, petitioners state that the production of PET Film utilizes very small amounts of fillers, which petitioners did not include in the normal value calculation. Petitioners state that they were unable to determine the correct tariff numbers in order to value these inputs, and not including them in the normal value calculation is a conservative approach. *See* PRC Petition at 42 and October 10, 2007 Supplemental Response at 8. With regard to energy (electricity), petitioners provided a surrogate value using the IEA's *Energy Prices & Taxes* 2007 (First Quarter) edition, which petitioners inflated to the POI, as the electricity value is based on the price paid by industrial users in India in 2000. *See* PRC Petition at 42 and Exhibits 17–18 and October 10, 2007 Supplemental Response at 8–9 and Exhibit 6. For labor, petitioners submitted a labor usage rate which was valued using the Department's NME Wage Rate for the PRC. For packing inputs, petitioners valued flanges, two–by-fours, and cores using Indian import statistics obtained through the *World Trade Atlas* from which they excluded data pertaining to NME and subsidy countries. *See* October 10, 2007 Supplemental Response at 10 and Exhibits 8 and 9; and October 15, 2007 Supplemental Response at 3. Petitioners asserted that pallets were utilized as a packing factor of production, but stated in their October 15, 2007 Supplemental Response that since they did not know the average weight of the pallets that form the basis of this HTS number in the Indian import statistics (as the surrogate value from the *World Trade Atlas* is based on rupees per piece), they removed the pallet expense. However, in their October 10, 2007 Supplemental Response at Exhibit 8, petitioners listed the weight of a typical pallet used to pack PET Film. We have applied this weight to the pallet surrogate value to derive a rupees per kilogram value and added this expense to normal value. *See PRC Initiation Checklist* at Attachment V for a revised pallet surrogate value.

For the normal–value calculations, petitioners derived the figures for factory overhead, selling, general, and administrative expenses, and profit from the financial ratios of three large Indian producers of PET Film: Flex Industries, Garware Polyester Limited, and Polyplex Corporation. The financial statements that petitioners provided covered the period of April 2005 to March 2006. Additionally, petitioners calculated a simple average of the three companies' financial ratios for purposes of the petition. *See* PRC Petition at 43 and Exhibit 20 and October 10, 2007 Supplemental Response at Exhibit 7. We did not make any other adjustments to the NV as calculated by the petitioners, other than the inclusion of pallets as a packing input. *See* Attachment V for the revised NV calculation.

Separate Rates for the Antidumping Investigation of Imports of PET Film from the PRC

In 2005, the Department modified the process by which exporters and producers may obtain separate–rate status in NME investigations. The Department's practice is discussed further in *Policy Bulletin 05.1:*

Separate–Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non–Market Economy Countries (April 5, 2005) (''*Separate Rates and Combination Rates Bulletin*''), available on the Department's website at *http://ia.ita.doc.gov/policy/bull05–1.pdf*. The process now requires the submission of a separate–rate status application. Based on our experience in processing the separate–rate applications in antidumping duty investigations, we have modified the application for this investigation to make it more administrable and easier for applicants to complete. *See, e.g., Initiation of Antidumping Duty Investigation: Certain New Pneumatic Off–the-Road Tires from the People's Republic of China*, 72 FR 43591, 43594–95 (August 6, 2007) (''*Tires from the PRC*''). The specific requirements for submitting the separate–rate application in this investigation are outlined in detail in the application itself, which will be available on the Department's website at *http://ia.ita.doc.gov/ia–highlights-and–news.html* on the date of publication of this initiation notice in the **Federal Register**. The separate–rate application is due no later than December 17, 2007.

Alleged U.S. Price and Normal Value: Thailand

For U.S. price, petitioners relied on a representative sale of Thai PET Film sold to a U.S. customer during the proposed POI. *See* Thailand Petition at Exhibit 22; Supplemental Response, dated October 9, 2007, at Exhibit 3. The price information supplied by petitioners was for 48 gauge packaging film, which falls within the scope of the petitions. Petitioners deducted from the price the costs associated with exporting and delivering the product, including a distributor mark–up (based on Flex America's financial statements), ocean freight and insurance charges, U.S. duty, port and wharfage fees, and U.S. inland freight. Additionally, petitioners deducted imputed credit expenses. We have adjusted the CEP price by recalculating the claimed distributor mark–up submitted by petitioners to eliminate line items which are being deducted separately from U.S. price. *See Thailand Initiation Checklist*.

For normal value, petitioners submitted price information for a home market sale obtained by an employee of a Thai PET Film reseller. *See* Thailand Petition at Exhibit 23; Supplemental Response, dated October 16, 2007, at Exhibit 4; and Supplemental Response, dated October 17, 2007, at Exhibit 1. However, complete information with respect to certain home market expense(s) were not reasonably available to the petitioners. As such, adequate home market prices were not reasonably available to petitioners; therefore, we have relied on petitioners' information for constructed value to calculate normal value. We are not initiating a sales below cost investigation because there are no home/comparison market sales. According to 19 CFR 351.301(d)(2)(i)(A), this will not preclude petitioners from filing a cost allegation once information becomes available.

Petitioners calculated constructed value for 48–gauge packaging film. With exception of FOH, SG&A expense, interest expense and profit rates, which were based on PTL's experience, petitioners calculated constructed value using PTL's cost of production using the experience of a U.S. producer of PET Film, adjusted for known differences between costs in Thailand and the United States. We recalculated petitioners' price–to-CV margin calculation to include an amount for packing. *See Thailand Initiation Checklist* for a detailed discussion on petitioners' calculation of CV.

Alleged U.S. Price and Normal Value: UAE

Petitioners calculated both a CEP and an export price (EP). Petitioners based CEP on a sale made by Flex UAE's U.S. affiliate, Flex America, to an unaffiliated customer during the proposed POI. The PET Film at issue is 92–gauge packaging film which, Petitioners explain, is a common and representative type of PET Film sold in the U.S. market and was sold on a ''Delivered, Duty Paid'' basis with 30 day payment terms. Petitioners deducted a distributor mark–up (based on Flex America's financial statements), international freight, U.S. Duty, U.S. inland freight, and U.S. credit. We have adjusted the CEP price by recalculating the claimed distributor mark–up submitted by petitioners to eliminate line items which are being deducted separately from U.S. price (*i.e.*, inland freight from the U.S. port to the distribution warehouse and brokerage charges).

Petitioners calculated EP on the POI weighted–average AUV customs value for PET Film imports from the UAE into the U.S. for subheading number 3920.62.00.90 of the Harmonized Tariff Schedule of the United States (HTS) based on Customs Value data collected from the USITC. *See UAE Initiation Checklist*.

For normal value, petitioners submitted price information for a home market sale which took place during the POI. However, complete information with respect to certain home market expense(s) were not reasonably available to the petitioners. As such, adequate home market prices were not reasonably available to petitioners; therefore, we have relied on petitioners' information for constructed value to calculate normal value. *See UAE Initiation Checklist* for a detailed discussion on petitioners' calculation of CV. We are not initiating a sales below cost investigation because there are no home/comparison market sales. According to 19 CFR 351.301(d)(2)(i)(A), this will not preclude petitioners from filing a cost allegation once information becomes available.

Petitioners calculated COM (except direct materials and fixed overhead) and packing expenses based on a U.S. producer's cost experience adjusted for known differences to manufacture PET Film in the UAE, using publicly–available data. *See* IEA publication, Energy Prices and Taxes for 2007: UAE's Regulation and Supervision Bureau publication of UAE energy costs from Industrial/Commercial rates for 2004. To calculate direct material, fixed overhead, SG&A and financial expense rates, petitioners relied on the most contemporaneous financial statements to the POI for a PET Film producer in the UAE. *See UAE Initiation Checklist*.

Petitioners valued raw materials using the per pound value of purchased polyester chips divided by the production quantity reported in FY 2006 financial statements of Flex UAE, a PET Film producer in the UAE. These were the most recent statement available. *See, e.g.*, the Supplement to the Petition, October 10, 2007, at page 8 and Exhibit 7.

Petitioners determined energy costs using the cost experience of a U.S. PET Film producer to manufacture one pound of PET Film, adjusted by the ratio of energy costs in UAE to that in the United States. Petitioners obtained the annual UAE energy costs for 2004 from the Industrial/Commercial rate published by the UAE's Regulation and Supervision Bureau and the annual U.S. energy costs for 2004 from the International Energy Agency publication, Energy Prices and Taxes for 2006. *See, e.g.*, the UAE Petition at page 65 and 66, and Exhibits 33 and 34.

To calculate labor, fixed overhead, SG&A expense, interest expense and profit, petitioners relied on the financial statements of Flex UAE for the fiscal year end December 31, 2006. We recalculated petitioners' price–to-CV margin calculation to include an amount for packing. *See, e.g.*, the UAE Petition at Exhibit 35, the supplement to the Petition, dated October 10, 2007, at

pages 10 and 11, and Exhibit 7 and Supplement to the Petition, dated October 15, 2007, at page 3 and Exhibit 5.

Respondent Selection and Quantity and Value Questionnaire for the PRC

In prior NME investigations, it has been the Department's practice to request quantity and value information from all known exporters identified in the PRC Petition. *See*, *e.g.*, *Initiation of Antidumping Duty Investigation: Certain New Pneumatic Off–the-Road Tires From the People's Republic of China*, 72 FR 43591 (August 6, 2007). For this investigation, because the HTSUS number 3920.62.00.90, as discussed above in the ''Scope of the Investigation,'' provides comprehensive coverage of imports of PET Film, the Department expects to select respondents in this investigation based on U.S. Customs and Border Protection (CBP) data of U.S. imports under HTSUS number 3920.62.00.90 during the POI.

Use of Combination Rates in an NME Investigation

The Department will calculate combination rates for certain respondents that are eligible for a separate rate in this investigation, pursuant to 19 CFR 351.107(b)(1). The *Separate Rates and Combination Rates Bulletin*, at 6, describes that, while continuing the practice of assigning separate rates only to exporters, all separate rates that the Department will now assign in its NME investigations will be specific to those producers that supplied the exporter during the POI. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the POI. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non–investigated firms receiving the weighted–average of the individually calculated rates. This practice is referred to as the application of ''combination rates'' because such rates apply to specific combinations of exporters and one or more producers. The cash–deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question and produced by a firm that supplied the exporter during the POI.

Fair–Value Comparisons

Based on the data provided by petitioners, there is reason to believe that imports of PET Film from Brazil, Thailand, the UAE, and the PRC are being, or are likely to be, sold in the United States at less than fair value. Based on comparisons of export price/constructed export price to normal value that we revised as discussed above and calculated in accordance with section 773(c) of the Act, these are the estimated dumping margins for PET Film: 1) the estimated dumping margins for Brazil range from 13.08 percent (price–to-price) to 44.36 percent (price to CV); 2) the estimated dumping margin for the PRC is 76.72 percent; 3) the estimated dumping margin for Thailand is 80.24 percent (price–to-CV); and 4) the UAE's estimated dumping margins range from 35.44 percent (EP–to-CV) to 73.23 percent (CEP–to-CV).

Initiation of Antidumping Investigations

Based upon the examination of the petitions on PET Film from Brazil, the PRC, Thailand, and the UAE and other information reasonably available to the Department, the Department finds that these petitions meet the requirements of section 732 of the Act. Therefore, we are initiating antidumping duty investigations to determine whether imports of PET Film from Brazil, the PRC, Thailand, and the UAE are being, or are likely to be, sold in the United States at less than fair value. In accordance with section 733(b)(1)(A) of the Act, unless postponed, we will make our preliminary determinations no later than 140 days after the date of this initiation.

Sales Below Cost Allegation

Petitioners have provided information demonstrating reasonable grounds to believe or suspect that sales of PET Film in Brazil were made at prices below the fully absorbed cost of production (COP), within the meaning of section 773(b) of the Act, and requested that the Department conduct a sales–below-costs investigation. We note that because petitioners were unable to provide adequate home market prices for Thailand or the UAE, we are not initiating country–wide cost investigations for those countries at this time. According to 19 CFR 351.301(d)(2)(i)(A), petitioners are not precluded from filing a cost allegation once the information becomes available.

An allegation of sales below COP need not be specific to individual exporters or producers. *See*, *e.g.*, Statement of Administrative Action accompanying the Uruguay Round Agreements Act, H.R. Doc. No. 103–316, Vol. 1 (1994) at 833. Thus, Commerce will consider allegations of below–cost sales in the aggregate for a foreign country. *Id.* Further, section 773(b)(2)(A) of the Act requires that the Department have ''reasonable grounds to believe or suspect'' that below–cost sales have occurred before initiating such an investigation. Reasonable grounds exist when an interested party provides specific factual information on costs and prices, observed or constructed, indicating that sales in the foreign market in question are at below–cost prices.

As described in the section below on ''Cost of Production and Constructed Value,'' the Department calculated a country–specific COP for a certain gauge of PET Film for Brazil. Based upon a comparison of the prices of the foreign–like product in the home market to the calculated COP of the product, we find reasonable grounds to believe or suspect that sales of the foreign like product were made below the COP, within the meaning of section 773(b)(2)(A)(i) of the Act. Accordingly, the Department is initiating a country–wide cost investigation with regard to Brazil. We note, however, that if we determine that the Brazilian home market is not viable, our initiation of a country–wide cost investigation with respect to sales in the home market will be rendered moot. *See Brazil Initiation Checklist*.

Cost of Production and Constructed Value (CV)

Pursuant to section 773(a)(4) of the Act, COP consists of the cost of manufacturing (''COM''); selling, general and administrative (SG&A) expenses; financial expenses; and packing.

Pursuant to section 773(a)(4) of the Act, petitioners calculated a single CV as the basis for normal value (NV). Petitioners calculated CV using the COM; SG&A expenses; financial expenses. Petitioners then added the average profit rate based on the most recent financial statements of a PET Film producer. *See Brazil Initiation Checklist*, *Thailand Initiation Checklist*, and *UAE Initiation Checklist*.

Brazil

Petitioners calculated COM and packing based on a U.S. producer's cost experience, adjusted for known differences (*e.g.*, energy and labor) to manufacture PET Film in Brazil using publically–available data. To calculate SG&A and financial expense rates, petitioners relied on the financial statements most contemporaneous to the proposed POI for a thermoplastic resins (including PET Film) producer in Brazil, Braskem Ltda. See Brazilian Initiation Checklist.Petitioners determined the cost of terephthalic acid (PTA) and mono–ethylene glycol (MEG) based on the quantities used to manufacture one pound of PET Film as

experienced by a U.S. PET Film producer. *See* Volume I of the Brazil Petition at page 32 and Volume II of the Brazil Petition at Exhibit 5. Petitioners stated the cost of the required raw material in Brazil were similar to that incurred by the U.S. PET Film producer and provided an affidavit in the Supplement to the Petition, dated October 10, 2007, at Exhibit 6 as support.

Petitioners determined labor costs using the labor cost experience of a U.S. PET Film producer to manufacture one pound of PET Film, adjusted by the ratio of labor costs in Brazil to those of the United States. Petitioners obtained the annual Brazilian and U.S. labor costs from the Department's ''Expected Wage Calculation: 2003,'' found at *http://ia.ita.doc.gov/wages/03wages/110805–2003–Tables* for Brazil and the United States. *See* Supplement to the Petition, dated October 10, 2007, at pages 9–10 and Exhibit 7.

Petitioners determined energy costs using the cost experience of a U.S. PET Film producer to manufacture one pound of PET Film, adjusted by the ratio of energy costs in Brazil to that of the United States. Petitioners obtained the annual Brazilian and U.S. energy costs from the International Energy Agency publication, Energy Prices and Taxes for 2004. *See* Volume I of the Petition at page 33 and Volume II of the Petition at Exhibits 5 and 9.

Petitioners determined the fixed overhead costs (exclusive of energy and labor) using the cost experience of a U.S. PET Film producer to manufacture one pound of PET Film. Petitioners' stated this was reasonable because the one producer of PET Film in Brazil does not publish its financial statements. *See* Volume I of the Brazil Petition at pages 33 and 34 and Supplement to the Petition, dated October 10, 2007, at page 8.

To calculate SG&A expense, interest expense and profit, petitioners relied on the financial statements of Braskem Ltda. for the fiscal year ended December 31, 2005, the most recent financial statements available. *See* Volume II of the Petition at Exhibit 10.

We recalculated fixed overhead costs based on the financial statements of Braskem Ltda. for the fiscal year ended December 31, 2005, as this best reflects the cost experience in Brazil. *See* Volume II of the Petition at Exhibit 10. To calculate a price–to-CV margin, we added packing to this revised CV. *See Brazil Initiation Checklist*.

Distribution of Copies of the Petitions

In accordance with section 732(b)(3)(A) of the Act, a copy of the public version of these petitions have been provided to the representatives of the Governments of Brazil, the PRC, Thailand, and the UAE. We will attempt to provide a copy of the public version of the petitions to the foreign producers/exporters named in the petitions.

International Trade Commission Notification

We have notified the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determination by the International Trade Commission

The ITC will preliminarily determine, no later than November 12, 2007, whether there is a reasonable indication that imports of PET Film from Brazil, the PRC, Thailand, and the UAE materially injure, or threaten material injury to, a U.S. industry. A negative ITC determination covering all classes or kinds of merchandise covered by the petitions would result in the investigations being terminated. Otherwise, these investigations will proceed according to statutory and regulatory time limits.

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: October 18, 2007.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E7–21120 Filed 10–25–07; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–428–830]

Notice of Initiation of New Shipper Antidumping Duty Review: Stainless Steel Bar from Germany

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') has received a request for a new shipper review of the antidumping duty order on Stainless Steel Bar (''SSB'') from Germany published on March 7, 2002 (67 FR 10382). In accordance with section 751(a)(2)(B) of the Tariff Act of 1930, as amended (''the Act''), and 19 CFR 351.214(d), we are initiating an antidumping new shipper review of Flanschenwerk Bebitz GmbH (''Flanschenwerk'').

EFFECTIVE DATE: October 26, 2007.

FOR FURTHER INFORMATION CONTACT: Brandon Farlander or Damian Felton, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–0182 or (202) 482–0133, respectively.

SUPPLEMENTARY INFORMATION: The Department received a timely request from Flanschenwerk, in accordance with 19 CFR 351.214(c), for a new shipper review of the antidumping duty order on SSB from Germany, which has a September semiannual anniversary month.

Pursuant to section 751(a)(2)(B)(i)(I) of the Act and 19 CFR 351.214(b)(2)(i), Flanschenwerk, an exporter and producer of the subject merchandise, certified that it did not export subject merchandise to the United States during the period of investigation (''POI'') (October 1, 1999, through September 30, 2000). Pursuant to section 751(a)(2)(B)(i)(II) of the Act and 19 CFR 351.214(b)(2)(iii)(A), Flanschenwerk also certified that since the initiation of the investigation it has not been affiliated with any exporter or producer who exported the subject merchandise to the United States during the POI, including those not individually examined during the investigation. Pursuant to 19 CFR 351.214(b)(2)(iv), Flanschenwerk also submitted documentation establishing the date on which its SSB was first shipped for export to the United States, the volume of that shipment, and the date of the first sale to an unaffiliated customer in the United States.

The Department conducted a query of the U.S. Customs and Border Protection (''CBP'') database to confirm that Flanschenwerk's shipment of subject merchandise had entered the United States for consumption and has been suspended for antidumping duties. The Department also corroborated Flanschenwerk's assertion that it made no subsequent shipments to the United States by reviewing CBP data.

Scope of the Order

For the purposes of this order, the term ''stainless steel bar'' includes articles of stainless steel in straight lengths that have been either hot–rolled, forged, turned, cold–drawn, cold–rolled or otherwise cold–finished, or ground, having a uniform solid cross section along their whole length in the shape of circles, segments of circles, ovals, rectangles (including squares), triangles, hexagons, octagons, or other convex polygons. SSB includes cold–finished stainless steel bars that are turned or ground in straight lengths, whether produced from hot–rolled bar or from

straightened and cut rod or wire, and reinforcing bars that have indentations, ribs, grooves, or other deformations produced during the rolling process.

Except as specified above, the term does not include stainless steel semi–finished products, cut length flat–rolled products (*i.e.*, cut length rolled products which if less than 4.75 mm in thickness have a width measuring at least 10 times the thickness, or if 4.75 mm or more in thickness having a width which exceeds 150 mm and measures at least twice the thickness), products that have been cut from stainless steel sheet, strip or plate, wire (*i.e.*, cold–formed products in coils, of any uniform solid cross section along their whole length, which do not conform to the definition of flat–rolled products), and angles, shapes and sections.

The SSB subject to this order is currently classifiable under subheadings 7222.11.00.05, 7222.11.00.50, 7222.19.00.05, 7222.19.00.50, 7222.20.00.05, 7222.20.00.45, 7222.20.00.75, and 7222.30.00.00 of the *Harmonized Tariff Schedule of the United States* (''HTSUS''). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Initiation of Review

Based on the information on the record and in accordance with section 751(a)(2)(B) of the Act and 19 CFR 351.214(d)(1), we have determined that Flanschenwerk has met the statutory and regulatory requirements for the initiation of a new shipper review. Thus, we are initiating a new shipper review of the antidumping duty order on SSB from Germany (produced and exported) by Flanschenwerk. Because we are initiating this new shipper review in the month immediately following the semiannual anniversary month, this review covers the period from March 1, 2007, through August 31, 2007, in accordance with 19 CFR 351.214(g)(1)(i)(B). We intend to issue the preliminary results of this review no later than 180 days after the date on which this review is initiated, and the final results within 90 days after the date on which we issue the preliminary results. *See* section 751(a)(2)(B)(iv) of the Act.

On August 17, 2006, the Pension Protection Act of 2006 (''H.R. 4'') was signed into law. Section 1632 of H.R. 4 temporarily suspends the authority of the Department to instruct CBP to collect a bond or other security in lieu of a cash deposit in new shipper reviews. Therefore, the posting of a bond under section 751(a)(B)(iii) of the Act in lieu of a cash deposit is not available in this case. Importers of SSB manufactured and exported by Flanschenwerk must continue to post cash deposits of estimated antidum ping duties on each entry of subject merchandise (*i.e.*, SSB) at the current all–others rate of 15.16 percent, established in *Implementation of the Findings of the WTO Panel in US–Zeroing (EC): Notice of Determination Under Section 129 of the Uruguay Round Agreements Act and Revocations and Partial Revocations of Certain Antidumping Duty Orders*, 72 FR 25261, 25262 (May 4, 2007).

Interested parties may submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305 and 351.306.

This initiation and notice are in accordance with section 751(a)(2)(B) of the Act, 19 CFR 351.214(d) and 19 CFR 351.221(c)(1)(i).

Dated: October 22, 2007.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E7–21109 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–808]

Stainless Steel Wire Rods From India: Preliminary Results of the Antidumping Duty New–Shipper Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: October 26, 2007.

SUMMARY: The Department of Commerce (the Department) is conducting a new–shipper review of the antidumping duty order on stainless steel wire rods (wire rods) from India manufactured and exported by Sunflag Iron & Steel Co., Ltd. (Sunflag). The period of review (POR) is December 1, 2005, through November 30, 2006. We preliminarily determine to apply adverse facts available to Sunflag's U.S. sales. We invite interested parties to comment on these preliminary results. Parties who submit argument in this proceeding are requested to submit with the argument (1) a statement of the issue and (2) a brief summary of the argument.

FOR FURTHER INFORMATION CONTACT: Catherine Cartsos or Minoo Hatten, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–1757 and (202) 482–1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 1, 1993, the Department published the antidumping duty order on stainless steel wire rods from India. See *Antidumping Duty Order: Certain Stainless Steel Wire Rods from India*, 58 FR 63335 (December 1, 1993). On December 29, 2006, the Department received a timely request from Sunflag for new–shipper and administrative reviews of the antidumping duty order, under section 751(a)(2)(B) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.214(c). On February 2, 2007, we published the initiation of the administrative review. On March 20, 2007, the Department published a notice of initiation of a new–shipper review of the antidumping duty order on stainless steel wire rods from India with respect to Sunflag. See *Stainless Steel Wire Rod From India: Notice of Initiation of Antidumping Duty New–Shipper Review*, 72 FR 13088 (March 20, 2007). On September 12, 2007, we published our intent to rescind the administrative review with respect to Sunflag because we are proceeding with the new–shipper review and because the administrative review covers entries during the same period of time as the new–shipper review. *See Stainless Steel Wire Rods from India: Preliminary Results of Antidumping Duty Administrative Review and Notice of Intent to Rescind Antidumping Duty Administrative Review in Part*, 72 FR 52079 (September 12, 2007). We conducted verification of Sunflag's information from July 30, 2007, through August 2, 2007. On August 8, 2007, we extended the time limit for the preliminary results of the new–shipper review to October 19, 2007. *See Stainless Steel Wire Rods From India: Extension of Time Limit for the Preliminary Results of the Antidumping Duty New–Shipper Review*, 72 FR 44496 (August 8, 2007).

Scope of the Order

The merchandise under review is stainless steel wire rods which are hot–rolled or hot–rolled annealed and/or pickled rounds, squares, octagons, hexagons or other shapes, in coils. Wire rods are made of alloy steels containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. These products are only manufactured by hot–rolling and are normally sold in coiled

form, and are of solid cross section. The majority of wire rods sold in the United States are round in cross–section shape, annealed, and pickled. The most common size is 5.5 millimeters in diameter.

The wire rods subject to this order are currently classifiable under subheadings 7221.00.0005, 7221.00.0015, 7221.00.0030, 7221.00.0045, and 7221.00.0075 of the *Harmonized Tariff Schedule of the United States* (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.

Bona Fide Analysis

Consistent with our practice, we investigated whether the two U.S. transactions reported by Sunflag during the POR were *bona fide* sales. Among the factors we examined was the relationship between Sunflag and its reported U.S. customer. Based on our investigation, we preliminarily determine that Sunflag's sales were made on a *bona fide* basis. For our complete analysis, see memorandum from Catherine Cartsos to the File entitled ''*Bona Fide* Nature of Sunflag Iron & Steel Co., Ltd.'s Sales in the New Shipper Review for Stainless Steel Wire Rods from India,'' dated October 19, 2007, on file in room B–099 of the main Department of Commerce building.

Use of Adverse Facts Available

Section 776(a)(2) of the Act provides that, if an interested party or any other person (A) withholds information that has been requested by the administering authority, (B) fails to provide such information by the deadlines for the submission of the information or in the form and manner requested, subject to subsections (c)(1) and (e) of section 782, (C) significantly impedes a proceeding under this title, or (D) provides such information but the information cannot be verified as provided in section 782(i), the administering authority shall, subject to section 782(d), use the facts otherwise available in reaching the applicable determination.

Section 782(d) of the Act provides that, if the Department determines that a response to a request for information does not comply with the request, the Department shall promptly inform the person submitting the response of the nature of the deficiency and shall, to the extent practicable, provide that person with an opportunity to remedy or explain the deficiency in light of the time limits established for the completion of the administrative review. Section 782(e) of the Act states that the Department shall not decline to consider information determined to be ''deficient'' under section 782(d) if all of the following requirements are met: (1) the information is submitted by the established deadline; (2) the information can be verified; (3) the information is not so incomplete that it cannot serve as a reliable basis for reaching the applicable determination; (4) the interested party has demonstrated that it acted to the best of its ability; and (5) the information can be used without undue difficulties.

Moreover, section 776(b) of the Act provides that, if the Department finds that an interested party has failed to cooperate by not acting to the best of its ability to comply with a request for information, the Department may use an inference adverse to the interests of that party in selecting from among the facts otherwise available. In addition, the Statement of Administrative Action accompanying the Uruguay Round Agreements Act, H.R. Doc. 103- 316, Vol. 1, at 870 (1994) (SAA), establishes that the Department may employ an adverse inference ''to ensure that the party does not obtain a more favorable result by failing to cooperate to the best of its ability than if it had cooperated fully.'' It also instructs the Department to consider, in employing adverse inferences, ''the extent to which a party may benefit from its own lack of cooperation.'' *Id.*

We preliminarily determine that Sunflag's questionnaire response of May 11, 2007, and supplemental questionnaire responses of June 26, 2007, and July 14, 2007, cannot serve as the basis for calculating a margin for Sunflag because we are unable to depend on the accuracy and reliability of the information in those responses. In our questionnaire we describe the form and manner in which the respondent should report its sales data. Specifically, we state,

> {f}or sales of merchandise that have been shipped to the customer and invoiced by the time this response is prepared, each ''record'' in the computer data file should correspond to an invoice line item (*i.e.*, each unique product included on the invoice). For sales of merchandise that have not yet been shipped and invoiced (in whole or in part) to the customer, a ''record'' should correspond to the unshipped portion of the sale. Each computer record submitted should contain the information requested concerning the product sold, the terms of the sale, the selling expenses incurred and other information.'' See *Questionnaire*, dated March 5, 2007, at B–3 and C–2.

As discussed in detail in the October 19, 2007, Memorandum entitled ''2005/2006 New–Shipper Review of Stainless Steel Wire Rods from India - Decision to Apply Adverse Facts Available and the Selection of an Appropriate Rate for the Preliminary Results of Review'' (AFA Memorandum), we found at verification that Sunflag did not report its sales in the home market as instructed. We found that, for its home–market database, Sunflag reported each invoice as a single observation even in those instances where the invoice contained multiple sales of different products (*i.e.*, multiple line items). Sunflag assigned the total invoice quantity and the total invoice value as the observation quantity and value, and it reported the product characteristics of only one of the line items as the product characteristics of the observation. Sunflag used the product description of the last item on the billing document (a different document from the invoice) to report the grade, diameter, further manufacturing, and gross unit price for the observation.

Also at verification we found discrepancies with certain variables Sunflag reported in the home–market and U.S. databases. We have insufficient information on the record to correct all of the discrepancies related to these variables. Moreover, Sunflag did not report most home–market expenses (four types of discounts, inland freight, commissions, indirect selling expenses, and variable cost of manufacturing in the home market) on a per–unit basis, as we requested in our questionnaire but, instead, reported them based on the total invoice quantity. In addition, because in its home–market database Sunflag reported each invoice as a single aggregated observation even in those instances where the invoice contained multiple sales of different products, the information it reported in most of the expense fields is inaccurate. For a detailed discussion with respect to these deficiencies see AFA Memorandum and memorandum from Catherine Cartsos and Edythe Artman to File entitled ''Verification of the Sales Response of Sunflag Iron & Steel Co., Ltd., in the Antidumping New–Shipper Review of Stainless Steel Wire Rod from India,'' dated October 19, 2007 (Verification Report). Therefore, Sunflag failed to provide information in the form and manner requested in the Department's original questionnaire. *See* section 776(a)(2)(B) of the Act.

A further flaw in Sunflag's information concerns our finding at the verification of the discrepancy between

the reported value of sales for the window period and the value of sales in the general ledger for the same period; the general–ledger figure was higher than the value Sunflag reported as its total home–market sales. Company officials attributed part of the difference in the two values to returns but, while part of the difference was indeed due to reporting sales net of returns, the remainder of the difference was due to sales of foreign like product that Sunflag should have reported but did not. By not reporting all of its sales of foreign like product, Sunflag withheld information that the Department requested in its questionnaire and two supplemental questionnaires. In addition, the Department officials observed while conducting verification that Sunflag maintained detailed records containing all the information necessary to provide a complete and accurate questionnaire response. See section 776(a)(2)(A) of the Act.

In addition to finding that Sunflag misreported and neglected to report home–market sales, Sunflag provided additional information that could not be verified. During the verification the Department officials found that Sunflag's reported sales data contained pervasive errors and much of the data remained substantially unverified due to Sunflag's lack of preparedness. Even though Sunflag officials received our Verification Agenda, which outlined in detail the steps we would follow at verification, more than a week in advance of the verification, they were not well prepared. Therefore, we experienced constant and serious delays while at verification. Because of these delays, it was impossible to verify all of the information we had identified as subject to our examination in the Verification Agenda. See section 776(a)(2)(D) of the Act.

Sunflag significantly impeded the new–shipper review by not providing accurate and necessary information contained in its records. See section 776(a)(2)(C) of the Act. Also, the Department can decline to consider information Sunflag submitted because, as demonstrated above, sections 782(e)(2) and (3) of the Act are not met. Accordingly, pursuant to sections 776(a)(2) of the Act, the use of total facts available for Sunflag is justified.

Section 776(b) of the Act provides that, if the Department finds that an interested party has failed to cooperate by not acting to the best of its ability to comply with a request for information, the Department may use an inference adverse to the interests of that party in selecting from among the facts otherwise available. See, *e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Affirmative Preliminary Determination of Critical Circumstance in Part: Prestressed Concrete Steel Wire Strand From Mexico*, 68 FR 42378 (July 17, 2003), unchanged in the final determination (see *Notice of Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances: Prestressed Concrete Steel Wire Strand from Mexico*, 68 FR 68350 (December 8, 2003)).

Sunflag had the documents necessary to report complete and correct information in the necessary and requested manner and format. Because it did not do so, we find that Sunflag did not act to the best of its ability in reporting necessary and accurate information and presenting its data in the requested manner that would enable us to calculate a margin. Therefore, we find it appropriate to use an inference that is adverse to Sunflag's interest in selecting from among the facts otherwise available. By doing so, we ensure that Sunflag will not obtain a more favorable rate by failing to cooperate.

Section 776(b) of the Act states that an adverse inference may include reliance on information derived from the petition. See also 19 CFR 351.308(c). We have preliminarily assigned Sunflag, as facts otherwise available with an adverse inference, the petition margin rate of 48.80 percent. While this is the highest margin in the history of the proceeding, it is also the all–others rate and, therefore, the rate currently applicable to entries of merchandise from Sunflag. Any rate lower than 48.80 percent would give Sunflag a more favorable rate despite its failure to cooperate to the best of its ability.

Section 776(c) of the Act requires that the Department corroborate, to the extent practicable, secondary information from independent sources that are reasonably at its disposal. Secondary information is defined as ''information derived from the petition that gave rise to the investigation or review, the final determination concerning the subject merchandise, or any previous review under section 751 concerning the subject merchandise.'' See SAA at 870. The SAA clarifies that ''corroborate'' means that the Department will satisfy itself that the secondary information to be used has probative value. See SAA at 870. The Department will examine, to the extent practicable, the reliability and relevance of the information. The SAA emphasizes, however, that the Department need not prove that the selected facts available are the best alternative information. See SAA at 869. The SAA also states that independent sources used to corroborate such evidence may include, for example, published price lists, official import statistics and customs data, and information obtained from interested parties during the particular investigation. See SAA at 870. See also19 CFR 351.308(d).

With respect to the reliability aspect of the corroboration, we will consider information reasonably at our disposal to determine whether a margin continues to be reliable and whether there are circumstances that would render data used as facts available unreliable. The 48.80 percent all–others rate from the investigation is the average of the rates applied to each original respondent in the investigation. In the investigation, the Department applied the highest rate among the margins in the petition to each respondent based upon a determination by the Department to use the best information available. See *Final Determination of Sales at Less Than Fair Value: Certain Stainless Steel Wire Rods from India*, 58 FR 54110, 54111 (October 20, 1993). The U.S. price in the petition, which resulted in the 48.80 percent rate, was based on a quote to a U.S. customer which was obtained through market research. See Memorandum from the analyst to the file dated October 19, 2007, entitled ''Transfer to Current Record of Petition for the Imposition of Antidumping Duties Dated December 29, 1993.''

The normal value the petitioner used in the petition was based on an actual home–market price quote from an Indian producer of stainless steel wire rods. The price quote for normal value in the petition was contemporaneous with the U.S. price quote in the petition as the basis for export price.

We determined that, because the home–market and U.S. price quotation reflected commercial practices of the particular industry during the period of investigation, the information was relevant to mandatory respondents which refused to participate in the investigation. No information has been presented in the current review that calls into question the reliability of this information nor has this rate been judicially invalidated. Further, the 48.80 percent rate was most recently corroborated and applied as an adverse facts–available rate to a respondent in the 2001–2002 review of this order. See *Stainless Steel Wire Rods from India: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review*, 68 FR70765,

70771 (December 19, 2003), unchanged in *Stainless Steel Wire Rods from India: Final Results and Partial Rescission of Antidumping Duty Administrative Review*, 69 FR29923 (May 26, 2004). Accordingly, we preliminarily determine that the rate we used in the investigation, which we corroborated in the 2001–2002 review of this order and in this review, is a reliable rate.

To assess the relevance of the petition margin for purposes of this review, in accordance with section 776(c) of the Act we examined the key elements of the calculations of export price and normal value upon which the petitioners based their margins for the petition, to the extent practicable. See *Certain Cut–to-Length Carbon Steel Plate from Mexico: Final Results of Antidumping Duty Administrative Review*, 64 FR 76, 84 (January 4, 1999).

In the current new–shipper review we were able to corroborate the U.S. price in the petition, which was used as the basis of the 48.80 percent rate, by comparing this price to information from a respondent in the concurrent administrative review covering the same POR, Mukand Limited (Mukand). Mukand's reported U.S. price is significantly lower than the U.S. price in the petition, thus corroborating the petition U.S. price. See Memorandum from the analyst to the file entitled, ''Placement of Mukand's Home–Market and U.S. Data on the Record,'' dated October 19, 2007 (Mukand Data Memo).

In the current new–shipper review, in order to corroborate normal value, we looked again at information from Mukand's response for the concurrent administrative review covering the same POR. We find that the home–market prices in Mukand's March 15, 2007, questionnaire response are similar to, and in many instances much higher than, the price provided as normal value in the 1992 petition, which contributed to the all–others rate of 48.80 percent. See Mukand Data Memo.

For these reasons, the Department considers the normal value to be corroborated. Furthermore, because the 48.80 percent rate is also the all–others rate for this order, Sunflag's shipments have entered the United States at this rate such that the 48.80 percent rate is relevant to the current POR.

Finally, this is a new–shipper review; hence, as the first review of Sunflag, there are no probative alternatives specific to the company. Accordingly, by using information that was applied in the less–than-fair–value investigation (LTFV), corroborated in the 2001–2002 review of this order, and preliminarily determined to be relevant to Sunflag in this review, we have corroborated the adverse facts–available rate ''to the extent practicable.'' See section 776(c) of the Act, 19 CFR 351.308(d).

Preliminary Results of Review

As a result of this review, we preliminarily determine that a dumping margin of 48.80 percent for Sunflag exists for the period December 1, 2005, through November 30, 2006.

Public Comment

We will disclose the documents resulting from our analysis to parties in this review within five days of the date of publication of this notice. Any interested party may request a hearing within 30 days of the publication of this notice in the **Federal Register**. If a hearing is requested, the Department will notify interested parties of the hearing schedule.

Interested parties are invited to comment on the preliminary results of this review. The Department will consider case briefs filed by interested parties within 30 days after the date of publication of this notice in the **Federal Register**. Interested parties may file rebuttal briefs, limited to issues raised in the case briefs. The Department will consider rebuttal briefs filed not later than five days after the time limit for filing case briefs. Parties who submit arguments are requested to submit with each argument a statement of the issue, a brief summary of the argument, and a table of authorities cited. Further, we request that parties submitting written comments provide the Department with a diskette containing an electronic copy of the public version of such comments.

We intend to issue the final results of this new–shipper review, including the results of our analysis of issues raised in the written comments, within 90 days after the date on which the preliminary results are issued.

Assessment Rates

The Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. Because we are relying on total adverse facts available to establish Sunflag's dumping margin, we preliminarily determine to instruct CBP to apply a dumping margin of 48.80 percent to all entries of subject merchandise during the POR that were produced or exported by Sunflag. The Department will issue instructions to CBP 15 days after the publication of the final results of review.

Cash-Deposit Requirements

The following cash-deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this new–shipper review, as provided by section 751(a)(1) of the Act: (1) the cash–deposit rate for Sunflag will be the rate established in the final results of this new–shipper review; (2) for previously investigated or reviewed companies not listed above, the cash–deposit rate will continue to be the company–specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the LTFV investigation but the manufacturer is, the cash–deposit rate will be the rate established for the most recent period for the manufacturer of the subject merchandise; and (4) the cash–deposit rate for all other manufacturers or exporters will continue to be the ''all others'' rate of 48.80 percent, which is the ''all others'' rate established in the LTFV investigation. See *Final Determination of Sales at Less Than Fair Value: Certain Stainless Steel Wire Rods from India*, 58 FR 54110, 54111 (October 20, 1993). These cash–deposit rates, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duites occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing this notice in accordance with sections 751(a)(2)(B) and 777(i)(1) of the Act and 19 CFR 351.214.

Dated: October 19, 2007.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E7–21106 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–890]

Wooden Bedroom Furniture From the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On July 30, 2007, the Department of Commerce (''Department'') issued its preliminary results in the changed circumstances review of the antidumping duty order on wooden bedroom furniture (''WBF'') from the People's Republic of China (''PRC''). *See Wooden Bedroom Furniture from the People's Republic of China: Preliminary Results of Antidumping Duty Changed Circumstances Review*, 72 FR 41492 (July 30, 2007) (''*Preliminary Results*''). For these final results, we continue to find that Tradewinds Furniture Ltd. is the successor–in-interest to Nanhai Jiantai Woodwork Co. (''Nanhai Jiantai''), and that Tradewinds International Enterprise Ltd. (''Tradewinds Intl'') is not the successor–in-interest to Nanhai Jiantai's affiliated exporter, Fortune Glory Industrial Limited (''Fortune Glory'').

EFFECTIVE DATE: October 26, 2007.

FOR FURTHER INFORMATION CONTACT: Juanita H. Chen or Robert A. Bolling, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: 202–482–1904 or 202–482–3434, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 18, 2007, in response to a joint request by Tradewinds Furniture Ltd. and Tradewinds Intl (collectively, ''Tradewinds''), the Department initiated a changed circumstances review to determine whether Tradewinds Furniture Ltd. and Tradewinds Intl are successors–in-interest to Nanhai Jiantai and Fortune Glory, respectively. *See Wooden Bedroom Furniture from the People's Republic of China: Initiation of Antidumping Duty Changed Circumstances Review*, 72 FR 2262 (January 18, 2007). On July 30, 2007, the Department issued its *Preliminary Results*, finding that Tradewinds Furniture Ltd. is the successor–in-interest to Nanhai Jiantai, and that Tradewinds Intl is not the successor–in-interest to Fortune Glory. See *Preliminary Results*, 72 FR 41492. As part of the Preliminary Results, the Department invited interested parties to submit case and rebuttal briefs, and provided the opportunity for parties to request a hearing. *See* 72 FR at 41495. On August 6, 2007, Tradewinds submitted a brief agreeing with the Department's finding for Tradewinds Furniture Ltd. but contesting the finding that Tradewinds Intl is not the successor–in-interest to Fortune Glory. No other parties submitted briefs. No interested parties submitted a rebuttal brief or requested a hearing.

Scope of Order

The product covered by the order is wooden bedroom furniture. Wooden bedroom furniture is generally, but not exclusively, designed, manufactured, and offered for sale in coordinated groups, or bedrooms, in which all of the individual pieces are of approximately the same style and approximately the same material and/or finish. The subject merchandise is made substantially of wood products, including both solid wood and also engineered wood products made from wood particles, fibers, or other wooden materials such as plywood, oriented strand board, particle board, and fiberboard, with or without wood veneers, wood overlays, or laminates, with or without non–wood components or trim such as metal, marble, leather, glass, plastic, or other resins, and whether or not assembled, completed, or finished.

The subject merchandise includes the following items: (1) wooden beds such as loft beds, bunk beds, and other beds; (2) wooden headboards for beds (whether stand–alone or attached to side rails), wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds; (3) night tables, night stands, dressers, commodes, bureaus, mule chests, gentlemen's chests, bachelor's chests, lingerie chests, wardrobes, vanities, chessers, chifforobes, and wardrobe–type cabinets; (4) dressers with framed glass mirrors that are attached to, incorporated in, sit on, or hang over the dresser; (5) chests–on-chests[1], highboys[2], lowboys[3], chests of drawers[4], chests[5], door chests[6], chiffoniers[7], hutches[8], and armoires[9]; (6) desks, computer stands, filing cabinets, book cases, or writing tables that are attached to or incorporated in the subject merchandise; and (7) other bedroom furniture consistent with the above list.

The scope of the order excludes the following items: (1) seats, chairs, benches, couches, sofas, sofa beds, stools, and other seating furniture; (2) mattresses, mattress supports (including box springs), infant cribs, water beds, and futon frames; (3) office furniture, such as desks, stand–up desks, computer cabinets, filing cabinets, credenzas, and bookcases; (4) dining room or kitchen furniture such as dining tables, chairs, servers, sideboards, buffets, corner cabinets, china cabinets, and china hutches; (5) other non–bedroom furniture, such as television cabinets, cocktail tables, end tables, occasional tables, wall systems, book cases, and entertainment systems; (6) bedroom furniture made primarily of wicker, cane, osier, bamboo or rattan; (7) side rails for beds made of metal if sold separately from the headboard and footboard; (8) bedroom furniture in which bentwood parts predominate[10]; (9) jewelry armories[11]; (10) cheval

[1] A chest-on-chest is typically a tall chest-of-drawers in two or more sections (or appearing to be in two or more sections), with one or two sections mounted (or appearing to be mounted) on a slightly larger chest; also known as a tallboy.

[2] A highboy is typically a tall chest of drawers usually composed of a base and a top section with drawers, and supported on four legs or a small chest (often 15 inches or more in height).

[3] A lowboy is typically a short chest of drawers, not more than four feet high, normally set on short legs.

[4] A chest of drawers is typically a case containing drawers for storing clothing.

[5] A chest is typically a case piece taller than it is wide featuring a series of drawers and with or without one or more doors for storing clothing. The piece can either include drawers or be designed as a large box incorporating a lid.

[6] A door chest is typically a chest with hinged doors to store clothing, whether or not containing drawers. The piece may also include shelves for televisions and other entertainment electronics.

[7] A chiffonier is typically a tall and narrow chest of drawers normally used for storing undergarments and lingerie, often with mirror(s) attached.

[8] A hutch is typically an open case of furniture with shelves that typically sits on another piece of furniture and provides storage for clothes.

[9] An armoire is typically a tall cabinet or wardrobe (typically 50 inches or taller), with doors, and with one or more drawers (either exterior below or above the doors or interior behind the doors), shelves, and/or garment rods or other apparatus for storing clothes. Bedroom armoires may also be used to hold television receivers and/or other audio-visual entertainment systems.

[10] As used herein, bentwood means solid wood made pliable. Bentwood is wood that is brought to a curved shape by bending it while made pliable with moist heat or other agency and then set by cooling or drying. *See* Customs' Headquarters' Ruling Letter 043859, dated May 17, 1976.

[11] Any armoire, cabinet or other accent item for the purpose of storing jewelry, not to exceed 24″ in width, 18″ in depth, and 49″ in height, including a minimum of 5 lined drawers lined with felt or

mirrors[12]; (11) certain metal parts[13];(12) mirrors that do not attach to, incorporate in, sit on, or hang over a dresser if they are not designed and marketed to be sold in conjunction with a dresser as part of a dresser–mirror set; and (13) upholstered beds[14].

Imports of subject merchandise are classified under subheading 9403.50.9040 of the HTSUS as ''wooden . . . beds'' and under subheading 9403.50.9080 of the HTSUS as ''other . . . wooden furniture of a kind used in the bedroom.'' In addition, wooden headboards for beds, wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds may also be entered under subheading 9403.50.9040 of the HTSUS as ''parts of wood'' and framed glass mirrors may also be entered under subheading 7009.92.5000 of the HTSUS as ''glass mirrors . . . framed.'' This order covers all wooden bedroom furniture meeting the above description, regardless of tariff classification. Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Final Results Of Review

As noted in the *Preliminary Results*, in a changed circumstances review involving a successor–in-interest determination, the Department typically examines several factors including, but not limited to, changes in: (1) management; (2) production facilities; (3) supplier relationships; and (4) customer base. *See Certain Cut–to-Length Carbon Steel Plate from Romania: Initiation and Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review*, 70 FR 22847 (May 3, 2005). While no single factor or combination of factors will necessarily be dispositive, the Department generally will consider the new company to be the successor to the predecessor if the resulting operations are essentially the same as those of the predecessor company. *See, e.g., Notice of Initiation of Antidumping Duty Changed Circumstances Review: Certain Forged Stainless Steel Flanges from India*, 71 FR 327 (January 4, 2006).

Analysis of Comments Received

Due to their proprietary nature, all issues raised in the post–preliminary comments by parties in this review (*i.e.*, whether Tradewinds Intl is the successor–in-interest to Fortune Glory) are addressed in the memorandum to the file, ''Decision Memorandum for the Changed Circumstances Review of Tradewinds Furniture Ltd. and Tradewinds International Enterprise Ltd. on the Antidumping Duty Order on Wooden Bedroom Furniture From the People's Republic of China,'' dated October 19, 2007 (''Decision Memorandum''). The Decision Memorandum is a proprietary document, for which a public version is available on file in the Central Records Unit in room B–099 of the main Department building.

Tradewinds Furniture Ltd.

Tradewinds concurs with the Department's preliminary findings with respect to the successorship of Tradewinds Furniture Ltd. Moreover, there has been no information submitted to the record that indicates the Department should change its finding with regards to Tradewinds Furniture Ltd. As a result, for the reasons stated in the *Preliminary Results*, we continue to find that Tradewinds Furniture Ltd. is the successor–in-interest to Nanhai Jiantai.

Therefore, we will instruct U.S. Customs and Border Protection to apply the cash deposit rate established for Nanhai Jiantai to all entries of merchandise exported by Tradewinds Furniture Ltd. The cash deposit determination from this changed circumstances review will apply to all entries of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this changed circumstances review. *See Notice of Final Results of Antidumping Duty Changed Circumstances Review; Certain Forged Stainless Steel Flanges From India*, 71 FR 31156, 31157 (June 1, 2006). This cash deposit rate shall remain in effect until further notice.

Tradewinds International Enterprise Ltd.

While Tradewinds asserts that its submitted documentation supports a finding that Tradewinds Intl is the successor–in-interest to Fortune Glory, and should be legally entitled to the Fortune Glory rate, we find that Tradewinds failed to provide sufficient evidence indicating that Tradewinds Intl is ''essentially the same'' as Fortune Glory for a successor–in-interest finding. Contrary to Tradewinds' argument, while we noted in our *Preliminary Results* that Fortune Glory has not transferred its export functions to Tradewinds Intl, it is not the sole reason we determined Tradewinds Intl is not essentially the same as Fortune Glory. Rather, the Department looks to a totality of the factors. While Tradewinds submitted some documentation to demonstrate the creation of Tradewinds Intl (including the business certification and naming of Tradewinds Intl), upon an examination of all the documentation submitted, against the factors required to support a finding of successor–in-interest, including proprietary factors that cannot be discussed in this public **Federal Register** notice, Tradewinds has failed to establish that such creation is essentially unchanged from Fortune Glory. *See* Decision Memorandum, at 3–6. Significantly, it is not possible to compare the factors the Department typically examines between the predecessor company Fortune Glory (*i.e.*, management, production facilities, supplier relationships, sales facilities, and customer base) to those of the

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felt-like material, at least one side door (whether or not the door is lined with felt or felt-like material), with necklace hangers, and a flip-top lid with inset mirror. *See* Issues and Decision Memorandum from Laurel LaCivita to Laurie Parkhill, Office Director, Concerning Jewelry Armoires and Cheval Mirrors in the Antidumping Duty Investigation of Wooden Bedroom Furniture from the People's Republic of China, dated August 31, 2004. *See also Wooden Bedroom Furniture from the People's Republic of China: Notice of Final Results of Changed Circumstances Review and Revocation in Part*, 71 FR 38621 (July 7, 2006).

[12] Cheval mirrors are, *i.e.*, any framed, tiltable mirror with a height in excess of 50″ that is mounted on a floor-standing, hinged base. Additionally, the scope of the order excludes combination cheval mirror/jewelry cabinets. The excluded merchandise is an integrated piece consisting of a cheval mirror, *i.e.*, a framed tiltable mirror with a height in excess of 50 inches, mounted on a floor-standing, hinged base, the cheval mirror serving as a door to a cabinet back that is integral to the structure of the mirror and which constitutes a jewelry cabinet lined with fabric, having necklace and bracelet hooks, mountings for rings and shelves, with or without a working lock and key to secure the contents of the jewelry cabinet back to the cheval mirror, and no drawers anywhere on the integrated piece. The fully assembled piece must be at least 50 inches in height, 14.5 inches in width, and 3 inches in depth. *See Wooden Bedroom Furniture From the People's Republic of China: Final Results of Changed Circumstances Review and Determination To Revoke Order in Part*, 72 FR 38621 (January 9, 2007).

[13] Metal furniture parts and unfinished furniture parts made of wood products (as defined above) that are not otherwise specifically named in this scope (*i.e.*, wooden headboards for beds, wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds) and that do not possess the essential character of wooden bedroom furniture in an unassembled, incomplete, or unfinished form. Such parts are usually classified under the Harmonized Tariff Schedule of the United States (''HTSUS'') subheading 9403.90.7000.

[14] Upholstered beds that are completely upholstered, *i.e.*, containing filling material and completely covered in sewn genuine leather, synthetic leather, or natural or synthetic decorative fabric. To be excluded, the entire bed (headboards, footboards, and side rails) must be upholstered except for bed feet, which may be of wood, metal, or any other material and which are no more than nine inches in height from the floor. *See Wooden Bedroom Furniture from the People's Republic of China: Final Results of Changed Circumstances Review and Determination to Revoke Order in Part*, 72 FR 7013 (February 14, 2007).

requesting company Tradewinds Intl because, as Tradewinds itself acknowledges, the successor–in-interest has yet to occur. Specifically, Tradewinds states that ''{n}o structural, management, employee, supplier, customer, or other changes are **anticipated** as a result of the transfer'' (emphasis added). Despite Tradewinds' assurances that operations will eventually be essentially the same, the Department cannot base a ruling on speculation, as it provides the Department with no record evidence to analyze. For a more detailed discussion, including relevant factors of a proprietary nature, see the Decision Memorandum.

As a result, we continue to find that Tradewinds Intl is not the successor–in-interest to Fortune Glory at this time and, therefore, should not be given the same antidumping duty treatment as Fortune Glory.

This notice is issued and published in accordance with sections 751(b)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 C.F.R. 351.216.

Dated: October 19, 2007.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E7–21101 Filed 10–25–07; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 062006A]

RIN 0648–XD10

Taking of Threatened or Endangered Marine Mammals Incidental to Commercial Fishing Operations; Issuance of Permit

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

ACTION: Notice.

SUMMARY: In accordance with the Marine Mammal Protection Act, NMFS hereby issues a permit for a period of 3 years to authorize the incidental, but not intentional, taking of three stocks of endangered marine mammals by the California/Oregon (CA/OR) drift gillnet fishery. The three stocks are: fin whale, California/Oregon/Washington (CA/OR/WA) stock; humpback whale, Eastern North Pacific (ENP) stock; and sperm whale, CA/OR/WA stock. This authorization is based in part on a determination that this incidental take will have a negligible impact on the affected marine mammal stocks.

DATES: This permit is effective for a 3–year period beginning October 26, 2007.

ADDRESSES: Copies of the reference materials may be obtained from Protected Resources Division, NMFS, Southwest Region, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213. Attention: Christina Fahy.

FOR FURTHER INFORMATION CONTACT: Monica DeAngelis, NMFS, Southwest Region, Protected Resources Division, (562) 980–3232 or Christina Fahy, (562) 980–4023.

SUPPLEMENTARY INFORMATION: Pursuant to the Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361, *et seq.*), NMFS is issuing a permit to authorize the taking of three stocks of endangered marine mammals (fin whale, California/Oregon/Washington (CA/OR/WA) stock; humpback whale, Eastern North Pacific (ENP) stock; and sperm whale, CA/OR/WA stock) incidental to the CA/OR drift gillnet fishery. This fishery is the only Category I or II fishery with a recent history of taking these three stocks of marine mammals, and in recent history this fishery has taken no other stocks of threatened or endangered marine mammals. Therefore, only this fishery and these three stocks of marine mammals are affected by this permit.

MMPA section 101(a)(5)(E) requires NMFS to allow the taking of marine mammals from species or stocks listed as threatened or endangered under the Endangered Species Act (ESA) (16 U.S.C. 1531 *et seq.*) incidental to commercial fishing operations if NMFS determines that: (1) incidental mortality and serious injury will have a negligible impact on the affected species or stock; (2) a recovery plan has been developed or is being developed for such species or stock under the ESA; and (3) where required under section 118 of the MMPA, a monitoring program has been established, vessels engaged in such fisheries are registered in accordance with section 118 of the MMPA, and a take reduction plan has been developed or is being developed for such species or stock.

MMPA section 101(a)(5)(E)(ii) requires NMFS to publish a list of the fisheries for which the necessary determinations have been made for the taking of threatened or endangered marine mammals incidental to the fisheries' operations. This list of fisheries currently contains the three fisheries that are the subject of this notice and identified in Table 1. The MMPA also requires NMFS, upon such determinations, to issue a permit to those fisheries in which vessels are required to be registered (Category I and II fisheries).

The 2007 List of Fisheries indicates that two Category III fisheries (CA lobster, prawn, shrimp, rock crab, fish pot and CA/OR/WA crab pot) have a history of taking humpback whales. NMFS is currently in the process of characterizing the trap and pot fisheries off the west coast of the United States and assessing the impact, based on the available information, to determine if reclassifying these fisheries is warranted. As provided by the MMPA, the taking of this stock of humpback whales would be authorized, if it were to occur and the owner or master of the vessel reported the take, as required by MMPA section 118(e). MMPA section 101(a)(5)(E)(ii) states that (1) permits are not required for Category III fisheries because participants are not required to register their vessels and (2) that after an appropriate negligible impact determination is completed, taking threatened or endangered marine mammals would not be a violation, so long as any injury or mortality is reported in accordance with MMPA section 118.

History of Applying Negligible Impact in Fisheries

Among the requirements of MMPA section 101(a)(5)(E) to issue a permit to take ESA-listed marine mammals incidental to commercial fishing, NMFS must determine whether the incidental taking from commercial fisheries would have a negligible impact on the affected stock or stocks of threatened or endangered marine mammals. Negligible impact determinations are required only in MMPA section 101(a)(5), and they are used in the procedures to authorize the take of small numbers of any stock of marine mammals incidental to activities other than commercial fishing (termed the ''Small Take Program'') and to permit the take of threatened or endangered marine mammals incidental to commercial fishing operations. That is, within the MMPA's provisions for the Small Take Program, NMFS must determine if the taking (by harassment, injury, and mortality) incidental to specified activities will have a negligible impact on the affected stocks of marine mammals (MMPA sections 101(a)(5)(A)(I) and 101(A)(5)(D)(i)(I)). For permitting the take of threatened or endangered marine mammals incidental to fishing operations, NMFS must determine if mortality and serious injury incidental to commercial fisheries will have a negligible impact on the affected species or stocks of

marine mammals (MMPA section 101(a)(5)(E)(i)(I)).

NMFS has implemented these programs through regulations and has relied upon qualitative and quantitative approaches to determine the levels of taking that would result in a negligible impact to affected stocks of marine mammals. The quantitative approach is more appropriate for serious injury and mortality than for non-lethal takes because mortality and serious injury are considered removals from the population and can be evaluated by well-documented models of population dynamics.

The MMPA does not define ''negligible impact.'' There is, however, a reference to negligible impact in the House of Representatives committee report for the MMPA Amendments of 1981. That report states, '''negligible' is intended to mean an impact which is able to be disregarded. In this regard, the committee notes that Webster's Dictionary defines the term 'negligible' to mean 'so small or unimportant or of so little consequence as to warrant little or no attention.''' (House of Representatives, Report 97–228, September 16, 1981). NMFS defined negligible impact in regulations for the Small Take Program (50 CFR 216.103) as ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.'' This qualitative definition indicates that detectable population-level effects are important features in negligible impact determinations.

This qualitative definition of negligible impact was the standard NMFS used to implement the Small Take Program from its inception in 1981 through 1994, when additional amendments to the MMPA required a more quantitative approach for assessing what level of removals from a population stock of marine mammals could be considered a negligible impact. It remains the only formal definition of negligible impact for implementing the MMPA, and its use was expanded in 1995 (see 50 CFR 229.2) to include determinations related to incidental taking from commercial fishing.

The MMPA Amendments of 1994 were enacted primarily to establish a regime to govern the taking of marine mammals incidental to commercial fishing operations, including MMPA section 101(a)(5)(E). These amendments were based in large part on a legislative proposal NMFS submitted to Congress in 1992. This legislative proposal was, in turn, based in large part on recommended guidelines, required by MMPA section 114, from the Marine Mammal Commission (Commission) in early 1990 (Recommended Guidelines to Govern the Incidental Taking of Marine Mammals in the Course of Commercial Fishing Operations after October 1993, transmitted to NMFS on July 12, 1990). In these guidelines, the Commission recommended, among five other characteristics of a mechanism to govern the take of threatened and endangered marine mammals incidental to fishing, '' the authorized level of take would have a negligible effect on population size and recovery time...'' The Commission provided initial quantitative guidance on negligible effect on population size and recovery time as the following: ''an effect that (a) will not cause or contribute to a further decline in distribution or size lasting more than twelve months; and/or (b) will not cause greater than a 10–percent increase in the best available estimate of the time it will take the affected species or population to recover to its maximum net productivity level.''

The first of the Commission's quantitative approaches is more appropriate for an activity that would have a relatively short duration relative to the life expectancy of the affected stocks of marine mammals and, in the case of commercial fishing, for the remote likelihood of serious injury or mortality by a Category III fishery. Where incidental mortality or serious injury may occur on a more regular basis, as expected for interactions with Category I or II commercial fisheries, the delay-in-recovery standard would be more appropriate.

NMFS has consistently used the Commission's delay-in-recovery guideline in distinguishing negligible from non-negligible impact. To apply this criterion, however, NMFS had to estimate what annual levels of removal would cause no more than a 10 percent delay in time to recovery. Such an effort was initiated at a NMFS-convened workshop (June 1994) to develop guidelines for preparing marine mammal stock assessment reports. Among the many items considered at that workshop, participants agreed that recovery factors (RF) used in the calculation of Potential Biological Removal (PBR) for each stock of marine mammals should compensate for uncertainty and possible unknown estimation errors. In discussing the RF for stocks of endangered species of marine mammals, participants noted that a RF of 0.1 would preserve 90 percent of net annual production for recovery of the stock, limiting the proportion of net annual production of the stock available for authorization of mortality or serious injury incidental to human-caused mortality. Participants also stated that reserving such a high proportion of net annual production of endangered species was appropriate to '' allow stocks to recover at near maximum rates, and to minimize the probability that naturally occurring stochastic mortality would result in extinction of the stock.'' (Barlow *et al.*, 1995). Workshop participants also noted, ''authorized levels of human-related mortality should increase recovery time of endangered stocks by no more than 10 percent (consistent with the goal stated in NMFS legislative proposal).'' (Barlow *et al.*, 1995). Consequently, participants at the workshop recommended, and NMFS accepted after public review and comment, that mortality and serious injury remaining at or below PBR for an endangered stock (with 0.1 as the RF in the PBR calculation) would have an insignificant or negligible impact on the affected stock.

In applying the negligible impact criterion to determinations made initially under the MMPA Amendments of 1994, NMFS understood that total human-caused mortality and serious injury limited to a level no greater than a PBR calculated with RF of 0.1 would be negligible; however, MMPA section 101(a)(5)(E) required a determination related to the impact of mortality and serious injury incidental to commercial fishing rather than incidental to all human activities. Accordingly, NMFS proposed to use, and subsequently used, 10 percent of any stock's PBR as the upper limit of mortality and serious injury incidental to commercial fishing in making the first negligible impact determinations (60 FR 31666, June 16, 1995 (proposed) and 65 FR 45399, August 31, 1995 (interim)). A rationale supporting this approach was that a negligible (or insignificant) level of fishery-related mortality and serious injury should be only a small portion of the maximum level of mortality and serious injury a stock could sustain. NMFS noted that the threshold value was a starting point; that is, the criterion should not be used rigidly but should produce the first estimate, which, in turn, could be modified on a case-by-case basis according to existing information. Although 10 percent of PBR was used in 1995 in issuing permits to fisheries under MMPA section 101(a)(5)(E), NMFS later became concerned that 10 percent of PBR may result in a much smaller number than the 10 percent-delay criterion would require (Wade and Angliss, 1997).

Later, Wade (1998) summarized the robustness trials conducted in support of the PBR approach for marine mammal conservation, including an aspect that was missing from simulations conducted for the NMFS-convened workshop in 1994: exploring the maximum level of annual removals from a population that would result in no more than a 10–percent delay in the time a population would need for recovery to its Maximum Net Productivity Level (MNPL). Wade (1998) found that an upper limit of annual removals equal to the value of a PBR calculation with a RF of 0.15 would allow 95 percent of simulations to equilibrate at or above MNPL, which was an initial step in quantifying the maximum number of annual removals resulting in a negligible impact. However, in some applications the negligible impact standard must also address a performance criterion for marine mammal stocks that are not necessarily depleted. Wade (1998), therefore, reported that an upper limit of annual mortality limited to a value equal to a PBR calculation with a RF of 0.1 would allow 95 percent of simulations to equilibrate within 95 percent of the carrying capacity of the affected stock of marine mammals.

Wade's (1998) performance testing included removals to the threshold level for a period of 100 years and evaluated the robustness of each case over a range of bias or uncertainty in productivity rates, abundance estimation, and mortality estimation. Thus, the limits are appropriate for use on long-term average removals and do not indicate that a short-term level of removal exceeding the threshold would delay time to recovery by more than 10 percent.

In 1998, NMFS published a notice (63 FR 71894, December 30, 1998) advising the public that NMFS was extending the 3–year permit issued to fisheries in 1995 to authorize the taking of threatened or endangered marine mammals. This notice also informed the public that NMFS considered the 6–month extension of the permit an opportunity to review existing criteria for the issuance of permits and to address issues that have arisen since the permits were first issued. NMFS solicited public comments to develop alternatives to 10 percent of PBR as a criterion for determining negligible impact; however, none were received.

Having received no comments upon which to develop alternatives for determining negligible impact, NMFS published a notice proposing to issue permits under MMPA section 101(a)(5)(E) in 1999 (64 FR 28800, May 27, 1999). The notice contained a statement that NMFS, through internal deliberation, had adopted the following criteria for making negligible impact determinations for such permits:

(1) The threshold for initial determination will remain at 0.1 PBR. If total human-related serious injuries and mortalities are less than 0.1 PBR, all fisheries may be permitted.

(2) If total human-related serious injuries and mortalities are greater than PBR, and fisheries-related mortality is less than 0.1 PBR, individual fisheries may be permitted if management measures are being taken to address non-fisheries-related serious injuries and mortalities. When fisheries-related serious injury and mortality is less than 10 percent of the total, the appropriate management action is to address components that account for the major portion of the total.

(3) If total fisheries-related serious injuries and mortalities are greater than 0.1 PBR and less than PBR and the population is stable or increasing, fisheries may be permitted subject to individual review and certainty of data. Although the PBR level has been set up as a conservative standard that will allow recovery of a stock, there are reasons for individually reviewing fisheries if serious injuries and mortalities are above the threshold level. First, increases in permitted serious injuries and mortalities should be carefully considered. Second, as serious injuries and mortalities approach the PBR level, uncertainties in elements such as population size, reproductive rates, and fisheries-related mortalities become more important.

(4) If the population abundance of a stock is declining, the threshold level of 0.1 PBR will continue to be used. If a population is declining despite limitations on human-related serious injuries and mortalities below the PBR level, a more conservative criterion is warranted.

(5) If total fisheries-related serious injuries and mortalities are greater than PBR, permits may not be issued.

Criterion 1 is the starting point for analyses. If this criterion is satisfied, the analysis would be concluded. The remaining criteria describe alternatives under certain conditions, such as fishery mortality below the negligible threshold but other human-caused mortality above the threshold, or fishery and other human-caused mortality between the negligible threshold and PBR for a stock that is increasing or stable. If criterion 1 is not satisfied, NMFS may use one of the other criteria, as appropriate.

In 2000, NMFS issued a permit to the CA/OR drift gillnet fishery to authorize the taking of threatened and endangered marine mammals incidental to its operation (65 FR 64670, October 30, 2000). For that permit, as for the current permit, NMFS used the criteria adopted in 1999 to distinguish between negligible and non-negligible impact on affected stocks of marine mammals.

Current Permit

Observer data, stranding records, and marine mammal reporting forms indicate the CA/OR drift gillnet fishery is the only Category I or II commercial fishery that takes the CA/OR/WA stocks of fin and sperm whales, and the ENP stock of humpback whales. However, based on stranding records, pot fisheries that operate in California (currently listed as Category III fisheries), may also take humpback whales.

On July 28, 2006 (71 FR 42809), NMFS proposed the issuance of a permit under MMPA section 101(a)(5)(E), for a period of 3 years, to authorize the incidental, but not intentional, taking of three stocks of threatened or endangered marine mammals (CA/OR/WA stocks of fin and sperm whales and the ENP stock of humpback whales) by the CA/OR drift gillnet fishery. That notice summarized documentation that: (1) a recovery plan has been developed or is being developed for the affected stocks, and (2) where required under section 118 of the MMPA, a monitoring program has been established, vessels engaged in such fisheries are registered, and a take reduction plan has been, or is being, developed.

The proposed permit indicated that recovery plans had been developed (humpback whales) or were being developed (fin and sperm whales). These recovery plans are available on the internet at the following address: *http://www.nmfs.noaa.gov/pr/recovery/plans.htm*. Accordingly, NMFS determined that recovery plans for the affected stocks are completed or being developed.

Vessels active in the fishery are registered under the MMPA each year, and an observer program has been in place in the CA/OR drift gillnet fishery since 1990 (see Description of the Fishery; Carretta *et al.*, 2006, Appendix 1. Descriptions of U.S. Commercial Fisheries) . Since the Pacific Offshore Cetacean Take Reduction Plan (POCTRP) was implemented in 1997 (62 FR 51805, October 3, 1997), observer coverage has been sufficient for reliable estimates of marine mammals mortality and serious injury. No other Category I or II fisheries, which are the only

commercial fisheries required to register, carry observers, or be subject to take reduction plans, have a history of taking these stocks of endangered whales. Accordingly, NMFS determined that, as required by MMPA section 118, vessels were registered under the MMPA, a monitoring program was in place, and a take reduction plan was in place for these stocks. Thus, all conditions for issuing a permit under MMPA section 101(a)(5)(E) are fulfilled.

In 2005, NMFS received an application for an Exempted Fishing Permit (EFP) for drift gillnet fishing from the Federation of Independent Seafood Harvesters to reopen the area closed in 2001 (described below) to drift gillnet fishing. The Pacific Fishery Management Council (PFMC) reviewed the EFP and facilitated the development of the permit conditions. These included: drift gillnet EFP fishing effort in the closure area would be limited to no more than 300 sets, and 100 percent observer coverage would be required, and up to 30 vessels would be eligible to participate. The permit included limits on the number of protected species that could be incidentally entangled in the drift gillnet EFP fishery. The PFMC recommended that NMFS issue the 2006 permit, and NMFS formally began review of the EFP, which included consultation under the ESA, to consider the impacts on ESA-listed species. The proposed 2006 EFP recommended by the PFMC for issuance was not issued. However, the PFMC recommended at their April 2007 meeting that NMFS issue this EFP in 2007 with the same terms and conditions as originally recommended for the 2006 application. On June 5, 2007, in a letter from NMFS to the PFMC, NMFS determined that it would not issue the permit for the proposed 2007 drift gillnet EFP, due to the potential for leatherback sea turtle mortalities that would result if the EFP were approved. If NMFS considers the issuance of a DGN EFP during the three years of this 101(a)(5)(E) permit, taking of listed marine mammal stocks considered under this permit would be covered under the existing analysis. The data analyzed in the negligible impact determination for this permit included years prior to 2001 when the currently closed area (requested to be opened under the EFP in 2006 and 2007) was open to fishing. Therefore, any taking of these stocks of marine mammals incidental to fishing under a similarly issued EFP (if it is granted) would be authorized by this permit. All drift gillnet fishing under an EFP would be subject to applicable requirements under the HMS FMP and would have to comply with the POCTRP. In addition, any proposed EFP application would be subjected to thorough review and analysis of impacts, in order to satisfy all mandated requirements under the ESA and the National Environmental Policy Act (NEPA).

Description of the Fishery

The CA/OR drift gillnet fishery operates primarily outside of state waters to about 150 nm offshore ranging from the U.S. Mexico border in the south to northward of the Columbia River, depending on sea surface temperature conditions. The 2007 List of Fisheries (72 FR 14466, March 28, 2007) estimated that there were 85 vessels in the fishery. This estimate of the number of vessels in the fishery is a historical reference based upon the number of vessels that indicated intent to participate in the fishery and may not be an accurate estimate of the number of vessels actively engaged in fishing in any given year. The drift gillnet fishery is a limited entry program, managed with gear, seasons, and area closures. In 2005, there were 90 fishing permits issued, and 42 vessels actively fished under their permit (Pacific Fishery Management Council 2006). More detailed information on the operation of this fishery is included in Appendix 2 of the final negligible impact determination associated with this permit.

Under California State regulations, the fishery is restricted to waters outside 200 nm from February 1 through April 30, and outside 75 nm from May 1 through August 14; the fishery is allowed to fish inside 75 nm from August 15 though January 31. In the portion of the U.S. EEZ off the Oregon coast, the fishery is closed throughout the year east of a line approximating 1000 fathoms. Because of these restrictions, vessels are not active during February, March, and April, and very little fishing effort occurs during the months of May, June, and July because CA/OR drift gillnet vessels targeting swordfish tend to set on warm ocean water temperature breaks, which do not appear along the California coast until late summer.

The fishery has been conducted under state and/or Federal regulations since MMPA section 118 was enacted. When the List of Fisheries under MMPA section 118 was first began, the CA/OR drift gillnet fishery was state-regulated. As a result, when NMFS promulgated regulations implementing the POCTRP (62 FR 51805, October 3, 1997), there were no other Federal actions associated with the fishery. For initial implementation of the take reduction plan, NMFS completed a consultation under ESA section 7 in September, 1997 (no jeopardy determination) and completed an Environmental Assessment under NEPA in August 1997. The regulatory requirements in the POCTRP included the use of extenders so that the upper part of the gillnet was 36 ft (10.9 m) below the surface and the use of acoustic warning devices (pingers) on nets.

As part of reasonable and prudent alternatives contained in a 2000 ESA consultation on the drift gillnet fishery, in 2001, a seasonal (15 August–15 November) area closure was implemented in the drift gillnet fishery north of Point Conception, to protect leatherback turtles that feed in the area and were observed entangled in previous fishing seasons. Additional seasonal/area closures in southern California have been established in the drift gillnet fishery to protect loggerhead turtles during declared or predicted El Nino years.

On February 4, 2004, NMFS partially approved the HMS FMP prepared by the PFMC. This FMP includes commercial fisheries using various gear types to target highly migratory species; however, only the drift gillnet fishery has a history of taking threatened or endangered marine mammals. Implementing regulations for the approved portions of the FMP were published on April 7, 2004 (69 FR 18444). The preamble to these regulations noted that an Environmental Impact Statement (EIS) had been prepared and filed with the Environmental Protection Agency and that a formal consultation under the ESA had been completed. These documents analyzed the effects of the fishery on the human environment and on threatened or endangered species.

The HMS FMP includes a permit requirement for vessels or vessel owners. Participants in the CA/OR drift gillnet fishery are also required to have a valid permit issued annually by the California Department of Fish and Game or Oregon Department of Fish and Wildlife, as applicable, depending upon where fishing occurs and landings are made. In accordance with MMPA section 118(c), only those vessels in the CA/OR drift gillnet fishery that have registered for a Marine Mammal Authorization Program (MMAP) are authorized to take marine mammals incidental to their fishing operations. Vessels holding this permit must comply with the POCTRP and implementing regulations.

Current Negligible Impact Determination

NMFS has evaluated the best available information for the three stocks listed as threatened or endangered under the ESA addressed by this permit and has determined (using data from 1998 through 2005 and computing a yearly average), on a stock-by-stock basis, whether the mortality and serious injury incidental to the CA/OR drift gillnet fishery is having a negligible impact on such stocks (NMFS 2006). Based on this assessment, using the 1999 criteria (see History of Applying Negligible Impact in Fisheries) for the three stocks of marine mammals addressed by this permit, NMFS concludes that the estimated mortality and serious injury incidental to commercial fishing will have a negligible impact on these stocks of fin, humpback, and sperm whales. A stock-by-stock summary of the negligible impact determination follows.

Fin Whale, CA/OR/WA Stock

The annual average serious injury and mortality to the CA/OR/WA stock of fin whales from all human-caused sources, including commercial fisheries (0.63 animals) plus ship strikes (0.88 animals), is 1.51 animals, which is 10 percent of this stock's PBR. Although criterion 1 states the threshold is less than rather than equal to 10 percent of PBR, there are circumstances that prompt NMFS to determine that this minor deviation from the guidelines is reasonable. The abundance of this stock is increasing, the PBR calculation uses a recovery factor of 0.1, and the serious injury and mortality is far below a level that would cause more than a 10 percent delay in recovery. During the past 16 years, only one fin whale has been observed taken by the CA/OR drift gillnet fishery (1999; which is after the implementation of the POCTRP and prior to the 2001 closure off California and Oregon), indicating that the likelihood that a fin whale would be taken in the CA/OR drift gillnet fishery is very low. NMFS estimates that total human-caused mortality and serious injury of fin whales will be less than 10 percent of the PBR of this stock. Therefore, mortality and serious injury of fin whales incidental to commercial fishing will have a negligible impact on the CA/OR/WA stock of fin whales under criterion 1.

Humpback Whale, ENP Stock

The annual average serious injury and mortality to the ENP stock of humpback whales from all human-caused sources, including commercial fisheries (1.5 animals) plus ship strikes (0.25 animals), is 1.75 animals, which is 76.1 percent of this stock's PBR (above the 0.1 PBR threshold, but below PBR). Although several humpback whales were entangled in recent years in crab pot gear and in unknown pot/net fisheries in California, the total fisheries-related serious injury and mortality is less than this stock's PBR. Since the beginning of the NMFS observer program in 1990, no mortalities or serious injuries of humpback whales have been attributed to the CA/OR drift gillnet fishery. No other Category I or II commercial fisheries have a history of causing mortality and serious injury of this stock. In addition, after the implementation of the POCTRP, overall cetacean entanglement rates in the drift gillnet fishery dropped considerably. Finally, the population for this stock is considered to be increasing by 6–7 percent per year (Carretta *et al.*, 2006). Because fishery-caused mortality and serious injury, in combination with other sources of human-caused mortality and serious injury, are below the PBR of an increasing stock, NMFS determines that mortality and serious injury incidental to commercial fisheries will have a negligible impact on the ENP stock of humpback whales using criterion 3.

Sperm Whale, CA/OR/WA Stock

The annual average serious injury and mortality to the CA/OR/WA stock of sperm whales from commercial fisheries (0.75 animals) plus ship strikes (0.38 animals), is 1.13 animals, which is 62.5 percent of this stock's PBR (above the 0.1 PBR threshold, but below PBR). The minimum population estimate for this stock is considered to be variable, with no obvious trend (Carretta *et al.*, 2006). However, the overall population of sperm whales has increased worldwide since it was listed under the ESA in 1973. Although it is difficult to determine a trend for the CA/OR/WA stock of sperm whales, this stock does not appear to be declining; therefore, it is either stable or increasing. The average annual fisheries-related mortality and serious injury for this stock is below PBR. Since the implementation of the POCTRP, only one sperm whale was incidentally taken (1998; taken prior to the 2001 closure off central California/southern Oregon) in the CA/OR drift gillnet fishery, but the net did not have a full complement of pingers; therefore, it is difficult to evaluate whether pingers have an effect on sperm whale entanglement. However, pingers have shown to have a positive effect on other odontocetes (i.e., lower entanglement rates) (Barlow and Cameron 2003). Further, there has not been a take of sperm whales since 1998 and the likelihood that a sperm whale would be taken by the CA/OR drift gillnet fishery is very low. Because the stock is stable or increasing and total human-caused mortality and serious injury is below PBR, NMFS determines that the mortality and serious injury incidental to commercial fisheries will have a negligible impact on the CA/OR/WA stock of sperm whales using criterion 3.

A permit is hereby issued to the CA/OR drift gillnet fishery authorizing the non-lethal taking of individuals from the CA/OR/WA stock of fin whales, the ENP stock of humpback whales, and the CA/OR/WA stock of sperm whales for a 3–year period. If NMFS determines at a later date that incidental mortality and serious injury from commercial fishing is having more than a negligible impact on these stocks, NMFS may use its emergency authority under MMPA section 118 to protect the affected stock or stocks and may modify the permit issued herein. In accordance with the MMPA, participants in Category III fisheries included in Table I are also authorized to take marine mammals from these three stocks of marine mammals so long as such taking is reported in accordance with MMPA section 118(d).

TABLE 1. LIST OF FISHERIES AUTHORIZED TO TAKE THREATENED AND ENDANGERED MARINE MAMMALS INCIDENTAL TO FISHING OPERATIONS.

Fishery	Category	Marine Mammal Stock
CA/OR Drift Gillnet Fishery	I	Fin whale, CA/OR/WA stock Humpback whale, ENP stock Sperm whale, CA/OR/WA stock
CA lobster, prawn, shrimp, rock crab, fish pot	III	Fin whale, CA/OR/WA stock Humpback whale, ENP stock Sperm whale, CA/OR/WA stock
WA/OR/CA crab pot	III	Fin whale, CA/OR/WA stock Humpback whale, ENP stock Sperm whale, CA/OR/WA stock

Comments and Responses

NMFS received six comment letters concerning the proposal for issuance of the 101(a)(5)(E) permit under the MMPA. All of these letters were in opposition to the issuance this permit. Two commenters expressed opposition to the issuance of a permit but did not explain the basis for their opposition. Therefore, these comments are not included the following summary of comments and responses.

Comment 1: Commenters stated that any fishing pursuant to the EFP would require a separate MMPA permit from NMFS.

Response: NMFS disagrees. The current 101(a)(5)(E) permit authorizes the taking of marine mammals incidental to the operation of the CA/OR drift gillnet fishery as it currently operates and would include fishing under an EFP, if proposed similarly to the application in 2006 and 2007 (i.e., fishing in the currently closed leatherback conservation area). The negligible impact determination included operation prior to 2001, when the affected area was open (see Current Negligible Impact); therefore, NMFS determined that commercial fishing, including that under an EFP, had it been approved, will have a negligible impact. The monitoring program would remain in place, vessels would be registered, and the take reduction plan would remain in effect. However, just as the current operation of the fishery required analysis under the ESA and NEPA, expanding effort through approval of a proposed EFP would require additional analyses pursuant to these statutes.

Comment 2: Commenters stated that NMFS improperly issued the October 2000 permit.

Response: NMFS disagrees. In the October 2000 permit (65 FR 64670), NMFS made all requisite determinations and followed the procedures for public comment required by MMPA section 101(a)(5)(E); therefore, the issuance of the 2000 permit was appropriate.

Comment 3: Commenters stated that the CA/OR drift gillnet fishery has continued to entangle ESA-listed marine mammals in the absence of a permit and, thus, has operated illegally for the past three years.

Response: NMFS disagrees. The MMPA permit addresses only the take of ESA-listed marine mammals incidental to the fishery rather than the operation of the fishery. One entanglement of a humpback whale occurred after the previous permit expired in 2003. The entangling net was out of compliance with regulations implementing the POCTRP. Thus, the participant in this fishery was not operating lawfully and take was not authorized. The event was reported for investigation. This 101(a)(5)(E) permit was initiated to ensure any future taking of threatened or endangered marine mammals is authorized in accordance with the ESA and MMPA.

Comment 4: Commenters expressed that NMFS cannot lawfully make a negligible impact determination for sperm whales because take is not below 10 percent of the PBR level. PBR for this stock is 1.8 whales per year, and the estimated take is 1.13 whales per year. Total mortality for sperm whales exceeds 10 percent of the PBR. The determinations for this permit are based upon the 1999 criteria, which are consistent with the objective to delay recovery by no more than 10 percent.

Response: NMFS disagrees. The MMPA contains no reference to 10 percent of PBR nor does it define negligible impact. The determinations for this stock was based upon criterion 3 as adopted in 1999 (see Current Negligible Impact Determination), which is consistent with the objective to delay recovery by no more than 10 percent.

Comment 5: Commenters questioned whether a permit could be issued under section 101(a)(5)(E) of the MMPA because there is insufficient evidence to support NMFS' determination that the CA/OR/WA sperm whale stock is stable or increasing because the population does not show obvious trends and since the level of mortality sustained by the stock is stated to be ''unknown'' or ''uncertain.'' NMFS cannot make a finding that the stock is stable or increasing. At best, the agency states that ''this stock does not appear to be declining.≥

Response: NMFS disagrees. As the comment notes, NMFS has established that the population is not decreasing; therefore, it is either stable or increasing. Although there remains some uncertainty related to the abundance of the population, the apparent trend for sperm whales in the Pacific Ocean is an increase, and this apparent increase is occurring even with current levels of mortality and serious injury.

Comment 6: Commenters remarked that NMFS cannot lawfully make a negligible impact determination for humpback whales because take is not below 10 percent PBR. The estimated take is 1.75 whales per year, but this is a gross underestimate. The PBR estimate is 2.3 whales per year. NMFS has substantial information on file that significant unobserved and/or unreported take is occurring. Commenters stated that NMFS needs to make the finding that the humpback whale stock ''is stable or increasing,'' not ''likely stable or increasing.≥

Response: NMFS disagrees that we cannot lawfully make a negligible impact determination, as noted in the response to comment 4. Although there are uncertainties in the mortality estimates, the performance of the delay in recovery criterion (Wade, 1998) is robust from bias and variance in mortality, as well as abundance estimates. According to the 2006 SARs and the best scientific information available, the Eastern North Pacific humpback whale stock is increasing in abundance, and NMFS has modified text in the Negligible Impact Determination to be clear that the population is ''stable or increasing.≥

Comment 7: Commenters remarked that NMFS cannot lawfully make a negligible impact determination for fin whales because take is ''at'' 10 percent PBR. These commenters noted that 1.5 fin whales injured and killed per year is not ''below'' 10 percent PBR, but rather it is 10 percent of the stock's PBR of 15. Commenters stated that NMFS needs to make the finding that the fin whale stock ''is stable or increasing,'' not ''likely stable or increasing.''

Response: NMFS disagrees. As noted in the response to comment 4, a lawful determination of negligible impact does not require reference to 10 percent of PBR. Total human-caused mortality and serious injury of this stock of fin whales is 10 percent of the stock's PBR, which is the threshold for negligible impact determinations. Due to the ''stable or increasing'' trend and the recovery factor of 0.1 in the PBR calculation for fin whales, this minor deviation from the specific wording of criterion 1 would not affect the over-arching goal to delay recovery by no more than 10 percent (see Current Negligible Impact Determination). Therefore, NMFS considered total human-caused mortality and serious injury at, rather than below, 10 percent of the stock's PBR to be a negligible impact. According to the 2006 SARs and the best scientific information available, the CA/OR/WA fin whale stock is increasing in abundance and NMFS has worded the Negligible Impact Determination to be clear that the population is ''stable or increasing.''

Comment 8: Commenters state that NMFS' calculations of total human-caused mortality and serious injury of fin, humpback, and sperm whales, is a gross underestimate, as most ship strikes go unreported and other fisheries that are known to entangle large whales remain unobserved.

Response: NMFS agrees that the total human-caused mortality and serious injury of fin, humpback, and sperm whales may be underestimates, but the agency used the best available data for our analysis in making the negligible impact determination. Although mortality may be underestimated, Wade (1998) showed that NMFS' basis for negligible impact determinations is robust to certain levels of underestimated mortality; therefore, NMFS determined that mortality and serious injury incidental to commercial fishing operations will have a negligible impact on these whale stocks.

Comment 9: Commenters stated that the deadline for Zero Mortality Rate Goal (ZMRG) has passed, and any take above ZMRG would be unlawful.

Response: NMFS disagrees and believes that this comment misinterprets the MMPA. The ZMRG, as described in Section 118 of the MMPA, has four parts. First, there is a threshold level of mortality and serious injury (insignificant levels approaching a zero mortality and serious injury rate) and a deadline by which commercial fisheries should reach the threshold. Second, there is a statement that fisheries that have achieved the threshold level of mortality and serious injury are not required to further reduce incidental mortality and serious injury. Third, there is a requirement for a review of fisheries progress toward the threshold. Fourth, there is a mechanism for reducing incidental mortality and serious injury (i.e., take reduction plans). Although the threshold and deadline are stated without condition, there is no statement in the MMPA that excess removals (mortality and serious injury exceeding threshold values after the deadline) cannot be authorized. The fourth part of the ZMRG states that these excess removals must be addressed through the take reduction plan process. NMFS has implemented a POCTRP as developed by a Pacific Offshore Cetacean Take Reduction Team (POCTRT) convened pursuant to MMPA section 118(f) and continues to keep that team intact until the threshold level of removals under the ZMRG has been achieved. NMFS convened a meeting of the POCTRT in April 2007 to evaluate the existing removal levels, to consider the economics of the fishery, the availability of existing technology, and existing fishery management plans, and to recommend, as appropriate, additional measures to further reduce incidental removals.

Comment 10: Commenters stated that it is unacceptable that the recovery plan for the humpback whale is 15 years old and the sperm and fin whales plan are in draft form.

Response: NMFS disagrees. Section 101(a)(5)(E) of the MMPA requires that ''a recovery plan has been developed or is being developed.'' Although, the humpback whale recovery plan was completed in 1991, NMFS maintains that this recovery plan is still effective, due in part to the documented increase in humpback whale populations in the Atlantic and Pacific Oceans (Carretta *et al.*, 2006, Waring *et al.*, 2006, and Angliss and Outlaw, 2006). NMFS announced the availability of draft recovery plans for fin and sperm whales on July 6, 2006 (71 FR 38385). Following a 60–day public comment period, NMFS is finalizing the sperm and fin whale recovery plans.

Comment 11: Commenters remarked that the proposed permit is inconsistent with the Guidelines for Assessing Marine Mammal Stocks (GAMMS) report and legislative intent (90 percent production reserved for recovery) and the proposed permit would waive the requirement that mortality not delay recovery by more than 10 percent. These commenters also stated that the proposal essentially renders the margin of safety created by the recovery factor meaningless and thereby reduces protection for listed species. In addition, commenters stated that the criteria are inconsistent with MMPA, that NMFS abandoned its previous ''more conservative approach'' (10 percent PBR in 1999) by adopting criteria based on internal review, and that the proposed permit further diminishes conservation for the most imperiled marine mammals.

Response: NMFS disagrees that the approach used here is inconsistent with NMFS' guidelines for preparing stock assessment reports or with legislative intent. The approach for determining negligible impact is consistent with the guidelines prepared by the Commission and submitted to NMFS in 1990 to be used in its development of a regime to govern the mortality and serious injury of marine mammals incidental to commercial fishing operations. In the guidelines, the Commission stated that a negligible impact should cause no more than a 10 percent delay in a severely depleted stock's recovery. Although this approach is less restrictive than a strict application of 10 percent of PBR as a threshold, the criteria adopted in 1999, which were applied in 2000 and used in this determination, are appropriate for a negligible impact determination because they fulfill NMFS' original objective to allow human-caused mortality and serious injury to cause no more than a 10 percent delay in the recovery of the affected stocks of marine mammals (see History of Applying Negligible Impact in Fisheries).

Comment 12: Commenters stated that the permit violates section 2(c) and 7(a)(1) of the ESA because the agency is required to use its authorities to further the purpose of listed species conservation. In addition, commenters noted that the ESA requires agencies to suspend activities that result in taking, and issuing a permit to continue to take without requiring additional measures to reduce bycatch violates the statutory directive to conserve listed species.

Response: NMFS disagrees. Issuance of this 101(a)(5)(E) permit is not a violation of either section 2(c) or 7(a)(1) of the ESA because this action would

authorize a level of take that would have a negligible impact on these three stocks of whales. Such an approach is consistent with the MMPA and is more restrictive than the ''jeopardy'' standard required in Section 7 of the ESA. The approach is also consistent with ESA section 2(c) because such a limit on mortality and serious injury promotes rapid recovery of the affected stocks; thus, NMFS is using its authority to promote the conservation and recovery of these species.

Comment 13: Commenters stated that the Steller sea lions should be included in the analysis.

Response: NMFS disagrees. Over the past 16 years, only two Steller sea lions have been observed taken by the drift gillnet fishery, one off southern California in 1992, and one off the CA/OR border in 1994. No Steller sea lions have been observed taken or reported entangled in drift gillnet gear since 1994. NMFS expects the entanglement of Steller sea lions in this fishery to be a rare event and not likely to occur within the next three years. Because taking Steller sea lions is not expected, this species was not included in the analysis, and no take of Steller sea lions is permitted.

Comment 14: Commenters stated that if NMFS intends to rely on the EIS prepared for the HMS FMP for compliance with NEPA, the agency must make the document available for review. Comments were provided previously on the significant legal flaws with that EIS.

Response: NMFS agrees that the EIS should be open to public comment. In accordance with the provisions of NEPA, NMFS solicited public comments on the Draft EIS (August 2003) for the HMS FMP and also solicited comments on the Final EIS in December 2003.

Comment 15: Commenters noted that numerous participants in the CA/OR drift gillnet fishery regularly operate in violation of applicable law and regulations. Rather than do anything about this gross non-compliance, NMFS simply assumes that compliance will be better this year. Given the flagrant disregard of MMPA provisions by the vessels in the fishery, commenters stated that NMFS must deny the permit to the fishery, or, at a minimum, suspend all other authorizations and permits for vessels in the fishery that have either not registered with NMFS as required under section 118(c) of the MMPA, or that have fished in violation of the POCTRP regulations. These commenters also noted that there are inconsistencies in the number of permit holders and expected number of participants in the fishery. NMFS indirectly admits that over 40 percent of the vessels in the fishery are violating registration requirements.

Response: NMFS disagrees that participants in this fishery regularly operate in violation of the law. The only specific violation described in the comment is a low proportion of the estimated number of participants are registered under the MMPA. This difference between estimated number of participants and the number of registered vessels does not reflect a violation of the law. As noted earlier in this notice (see Description of the Fishery), the estimated number of participants is based on a historical record of the number of individuals who have expressed intent to fish. Such an intent does not necessarily mean that there was active fishing by that vessel. Rather, the vessel owner or captain may have fished in the past or expressed intent to fish in the past; however, this vessel was not actively fishing in the affected year. Consequently, the number of registered vessels is lower than the estimated number of participants.

Comment 16: One commenter stated that fishing under the proposed EFP will undoubtedly kill endangered marine mammals, and, therefore, authorization under both the ESA and MMPA is required. The proposed permit makes no mention of the EFP, while in several places it mentions the leatherback closure as a likely factor in reducing marine mammal take to levels that NMFS feels it can make a negligible impact determination. This commenter noted that NMFS cannot rely on these 2004 documents for ESA and NEPA compliance (in reference to the HMS FMP EIS and biological opinion (BO)), and that NMFS would have to carry out a new consultation on the FMP as a whole and issue and circulate a new draft EIS for public comment. In addition, the commenter stated that NMFS cannot claim that the new ESA consultation it is currently carrying out for the EFP would also be sufficient for the MMPA permit.

Response: NMFS disagrees that expanding fishing effort, as proposed in the 2006 and 2007 EFP application, would undoubtedly result in deaths of endangered marine mammals. Takes through this fishing activity that result in mortality are rare events, and there is very limited additional effort requested under the EFP. If NMFS and/or the PFMC considers a DGN EFP in the future, as similarly proposed in 2006 and 2007, a section 7 consultation and all other applicable analyses would need to be completed before issuance.

Comment 17: One commenter expressed that NMFS states that it will rely on the February 2004 BO for the HMS FMP. This commenter noted that no take of ESA-listed marine mammals was authorized in this BO. Nevertheless, take of humpback whales has occurred since the BO. The commenter stated that therefore, the reinitiation requirements have been triggered.

Response: NMFS disagrees. The 2004 BO for the HMS FMP included an Incidental Take Statement which estimated the anticipated incidental take of listed species in the HMS fisheries. The estimated entanglement of fin, humpback, and sperm whales was 4 animals in 3 years, per species. The estimated mortality of fin and sperm whales was 2 animals in 3 years, per species. There were no anticipated mortalities of humpback whales. The entangled humpback whale in 2004 was released alive and uninjured. However, the net used was not in full compliance with the POCTRP (NMFS Observer Program 2006), and therefore not in compliance with the incidental take statement, which anticipates take during lawful activity. Because the take did not occur incidental to a lawful activity, the incidental take statement is not applicable, and no violation occurred. As mentioned earlier, this incident has been forwarded to the NMFS Southwest Regional Office of Law Enforcement for investigation. This permit was initiated to ensure that taking marine mammals incidental to the fishery was consistent with the MMPA as well as the ESA.

Comment 18: One commenter expressed concern that observer coverage for the rest of the fishery would be limited and that there is no assurance that sufficient observer coverage can be maintained, due to 100 percent observer coverage required for EFP.

Response: Observer coverage for the current drift gillnet fishery averages at least 20 percent per year. NMFS expects to maintain this level of coverage even if an EFP is issued.

Comment 19: One commenter stated that the permit is only being issued to support the EFP. The commenter noted that NMFS should properly conduct the negligible impact analysis and should not rush its analysis for the sake of approving the EFP.

Response: The permit is being issued to fulfill NMFS' obligations under MMPA section 101(a)(5)(E). The analysis of the CA/OR drift gillnet observer data from 1998–2005 resulted in a negligible impact determination for the CA/OR/WA stocks of fin and sperm whales and ENP stock of humpback whales. The negligible impact analysis

was a deliberate process that took more than a year to complete and ensures that the DGN is operating consistent with the requirements of the ESA and the MMPA.

Comment 20: Commenters stated that criterion 1 is not appropriate criteria to use for fin whales; therefore, it is improper to make a negligible impact determination under criterion 1 and that NMFS must move to perform analysis under criterion 2.

Response: NMFS disagrees. In applying the 1999 criteria, NMFS uses criterion 1 as the starting point for the analyses. If this criterion is satisfied, the analysis would be concluded. If criterion 1 is not satisfied, NMFS may use one of the other criteria, as appropriate. Total human-caused mortality of this stock of fin whales does not exceed the threshold, and, as noted earlier (see History of Applying Negligible Impact in Fisheries and Current Negligible Impact Determination), there are other factors (e.g., recovery factor in the PBR calculation and the trend in abundance of the stock) supporting the use of criterion 1.

Comment 21: Commenters stated that criterion 1 is not appropriate to use for humpback whales; therefore it is improper to find under criterion 1. Commenters questioned whether a finding under criterion 3 was appropriate because of ''certainty of data.'' Criterion 3 should be applied in a conservative manner, and NMFS should not overlook significant sources of uncertainty (human-cause injury and mortality). NMFS' declaration that mortality and serious injury caused by Category I and II fisheries will not delay recovery time by more than 10 percent is irrelevant, as criterion 3 looks to ''total fisheries-related serious injuries and mortalities.≥

Response: NMFS applied criterion 3, not criterion 1, to assess the total fisheries-related serious injury and mortality to the humpback whale and adjusted the Negligible Impact Determination accordingly. Criterion 3 is appropriate when the affected population is stable or increasing and human-caused mortality is above 10 percent of PBR but less than PBR. These conditions were satisfied in this case; therefore, criterion 3 was appropriate.

Comment 22: Commenters remarked that with regard to the fin whale, under criterion 2, non-fisheries related mortality must have already been addressed with specific ''management measures,'' before a permit can be issued.

Response: As noted earlier (see History of Applying Negligible Impact in Fisheries), criterion 1 is the starting point for negligible impact analyses, and the others are used only if this criterion is not satisfied. In this case, criterion 1 was satisfied (human-caused mortality did not exceed 10 percent of PBR); therefore, NMFS did not use criterion 2, which is premised on total human-caused mortality exceeding 10 percent of PBR.

Comment 23: Commenters stated that management measures do not exist or are not intended to address the mortality of these three species. Pingers are not effective in preventing mysticete entanglements and have not been proven effective and/or the effectiveness of pingers is not well understood for sperm whales.

Response: NMFS disagrees that management measures are not in place to address the mortality of these three species. The POCTRP contains many regulatory and non-regulatory measures designed to reduced mortality and serious injury of marine mammals. Since implementation of the POCTRP, mortality and serious injury of marine mammals incidental to the gillnet fishery are lower than in years prior to the POCTRP.

Comment 24: One commenter noted that there was no plan to reduce ship strikes on the west coast.

Response: NMFS Southwest Regional Office is working with the U.S. Coast Guard to develop a system to report sightings and location of marine mammals, large cetaceans in particular, and notify mariners of the presence and location of such marine mammals.

Comment 25: One commenter stated that ship-related deaths of large cetaceans go largely undetected in the absence of thorough necropsies of dead stranded animals. Dead or stranded humpback whales are not routinely necropsied throughout the range of this stock.

Response: NMFS acknowledges that there are uncertainties in assigning cause of death in many stranded marine mammals, generally due to decomposition of tissues and that necropsies are an important tool in helping to determine cause of death. Members of the marine mammal stranding network perform necropsies on marine mammals throughout the west coast region, when possible.

Comment 26: One commenter stated that just because enforcement was lax enough that a take occurred in an illegal net, this does not obviate risk to species.

Response: NMFS considered all mortality and serious injury, including the incident noted in this comment (the humpback whale was incidentally taken, but released alive and uninjured in 2004), in the current negligible impact determinations for the fin, sperm, and humpback whales. NMFS forwarded the incident in question to the Southwest Region's Office of Law Enforcement.

Comment 27: Commenters expressed that issuance of the proposed permit would violate two requirements of the National Marine Sanctuaries Act: to avoid injury to Sanctuary resources and to consult with the National Ocean Service about potential effects on Sanctuary resources. The fishery overlaps the boundaries of three national marine sanctuaries. The fin, humpback, and sperm whales are all resources protected by these sanctuary designations. Fishing under the proposed permit would clearly ''destroy, cause the loss, or injure'' these resources.

Response: The fishery overlaps four sanctuaries. NMFS consults with staff in the affected sanctuaries to ensure fishery operations are consistent with all relevant statutory and regulatory provisions.

Dated: October 23, 2007.

Helen M. Golde,

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

[FR Doc. E7–21091 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD61

Marine Mammals; File No. 10080

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Dr. Kathryn A. Ono, Department of Biological Sciences, University of New England, Biddeford, ME, has applied in due form for a permit to conduct research on marine mammals.

DATES: Written, telefaxed, or e-mail comments must be received on or before November 26, 2007.

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)427–2521; and

Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2298; phone (978)281–9300; fax (978)281–9394.

Written comments or requests for a public hearing on this application should be mailed to the Chief, Permits, Conservation and Education Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate.

Comments may also be submitted by facsimile at (301)427–2521, provided the facsimile is confirmed by hard copy submitted by mail and postmarked no later than the closing date of the comment period.

Comments may also be submitted by e-mail. The mailbox address for providing e-mail comments is *NMFS.Pr1Comments@noaa.gov*. Include in the subject line of the e-mail comment the following document identifier: File No. 10080.

FOR FURTHER INFORMATION CONTACT: Tammy Adams or Jaclyn Daly, (301)713–2289.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant requests a 5–year permit to examine expanding populations of the Western North Atlantic stocks of harbor seals (*Phoca vitulina concolor*) and grey seals (*Halichoerus grypus*) in the Gulf of Maine. The objectives of the study are to assess the state of harbor seal population health; determine movement and diving patterns of weaned harbor seal pups; compare disease loads, survival, and behavior of rehabilitated harbor seal pups with wild pups; and assess behavior, population dynamics, and health of grey seals. The research would involve capture of up to 200 harbor seals and 500 grey seals annually for attachment of flipper tags, physical examinations, and tissue sampling to assess health, behavior, and population dynamics. Up to 10 of the 400 harbor seals captured annually would have satellite tags attached for recording data on movement and dive patterns. An additional 100 grey seals annually may be remotely marked with paint or hair dye to facilitate behavioral observations. Up to 400 harbor seals, 2500 grey seals, 150 harp seals (*Pagophilus groenlandicus*), and 150 hooded seals (*Cystophora cristata*) may be harassed annually incidental to capture and sampling. The applicant has requested authorization for the unintentional research related mortality of up to 2 harbor seals and 4 grey seals annually.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), NMFS has initially determined that issuance of the proposed permit is consistent with a category of activities identified in NOAA Administrative Order 216–6 that do not individually or cumulatively have the potential to pose significant impacts on the quality of the human environment and are therefore exempted from further environmental review and requirements to prepare environmental review documents.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: Ocrober 23, 2007.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E7–21096 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD35

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to a U.S. Navy Shock Trial

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

ACTION: Notice; receipt of application for implementation of regulations and a letter of authorization; request for comments and information.

SUMMARY: NMFS has received a request from the U.S. Navy (Navy) for implementation of regulations and an authorization for the taking of marine mammals incidental to conducting a Full Ship Shock Trial (FSST) of the MESA VERDE (LPD–19) in the offshore waters of the Atlantic Ocean off Mayport, FL. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is announcing our receipt of the Navy's request for the development and implementation of regulations governing the incidental taking of marine mammals and inviting information, suggestions, and comments on the Navy's application and request.

DATES: Comments and information must be received no later than November 26, 2007.

ADDRESSES: Comments on the application should be addressed to Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225. The mailbox address for providing email comments is *PR1.XD35@noaa.gov*. NMFS is not responsible for e-mail comments sent to addresses other than the one provided here. Comments sent via e-mail, including all attachments, must not exceed a 10–megabyte file size.

A copy of the Navy's application may be obtained by writing to the address specified above (See **ADDRESSES**), telephoning the contact listed above (see **FOR FURTHER INFORMATION CONTACT**), or visiting the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm*.

FOR FURTHER INFORMATION CONTACT: Ken Hollingshead, Office of Protected Resources, NMFS, (301) 713–2289, ext. 128.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (Secretary) to allow, upon request, the incidental, but not intentional taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) if certain findings are made and regulations are issued or, if the taking is limited to harassment, notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings will be granted if NMFS finds that the taking will have a negligible impact on the affected species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for certain subsistence uses, and if the permissible methods of taking and the requirements pertaining to the mitigation, monitoring and reporting of such taking are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

With respect to military readiness activities, the MMPA defines ''harassment'' as:

(i) any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild [Level A Harassment]; or (ii) any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered [Level B Harassment].

Summary of Request

On June 25, 2007, NMFS received an application from the Navy requesting implementation of regulations and authorization for the taking of marine mammals incidental to its conducting an FSST during a four-week period in the spring/summer of 2008 utilizing the MESA VERDE (LPD 19), a new amphibious transport dock ship. The shock trial of the MESA VERDE would consist of up to four underwater detonations of a nominal 4,536 kilogram (10,000 lb) charge at a rate of one detonation per week. The purpose of the proposed action is to generate data to assess the survivability of SAN ANTONIO Class amphibious transport dock ships. An entire manned ship must undergo an at-sea shock trial to obtain survivability data that are not obtainable through computer modeling and component testing on machines or surrogates. Navy ship design, crew training, and survivability lessons learned during previous shock trials, and total ship survivability trials, have proven their value by increasing a ship's ability to survive battle damage.

Each new class of surface ships must undergo realistic survivability testing to assess the survivability of the hull and the ship's systems, and to evaluate the ship's capability to protect the crew from an underwater explosion. The Navy has developed the shock trial to meet its obligation to perform realistic survivability testing. A shock trial consists of a series of underwater detonations that propagate a shock wave through the ship's hull under deliberate and controlled conditions. The effects of the shock wave on the ship's hull, equipment, and personnel safety features are then evaluated. This information would be used by the Navy to validate or improve the survivability of the SAN ANTONIO Class, thereby reducing the risk of injury to the crew, and damage to or loss of a ship. The proposed shock trial qualifies as a military readiness activity as defined in Section 315(f) of Public Law 107–314; 16 U.S.C. 703 note.

Marine Mammals

A summary of the marine mammal species found in the Mayport, FL, area is presented here. For more detail on marine mammal abundance, density and the methods used to obtain this information, reviewers are requested to refer to either the Navy application or the Navy DEIS (see **ADDRESSES**). Up to 29 marine mammal species may be present in the waters off Mayport, FL, including 7 mysticetes and 22 odontocetes. Mysticetes are unlikely to occur at Mayport during the spring or summer time period. Odontocetes may include the sperm whale, dwarf and pygmy sperm whale, 4 species of beaked whales, and 15 species of dolphins and porpoises.

Potential Impacts

Potential impacts on several marine mammal species known to occur in the area offshore of Mayport, FL from shock testing include both lethal and non-lethal injury, as well as harassment. Death or injury may occur as a result of the explosive blast, and injury may occur as a result of non-injurious physiological responses to the explosion-generated shockwave and its acoustic signature. The Navy believes it is very unlikely that injury will occur from exposure to the chemical by-products released into the surface waters, and no permanent alteration of marine mammal habitat would occur. While the Navy does not anticipate any lethal takes would result from these detonations due to mitigation and monitoring measures that are proposed to be undertaken by the Navy, marine mammal density-based calculations indicate that the Mayport site has the potential to result in up to 1 mortality, 2 Level A harassments (injuries), and 282 takings by Level B (behavioral) harassment.

Mitigation

The Navy's proposed action includes mitigation that would minimize risk to marine mammals and sea turtles. The Navy proposes to (1) through pre-detonation aerial surveys, select a test area within the chosen site location with the lowest number of marine mammals and sea turtles; (2) monitor the area visually (aerial and shipboard monitoring) before each test and postpone detonation if any marine mammal is detected within a range that has a potential to cause injury; and (3) monitor the area after each test to locate any injured animals. If post-detonation monitoring shows that marine mammals were killed or injured as a result of the test, testing would be halted until procedures for subsequent detonations could be reviewed and changed as necessary. NMFS may propose and require additional mitigation through its rulemaking and Endangered Species Act (ESA) consultation.

NEPA

The Navy has released a Draft Environmental Impact Statement (Draft EIS) for the MESA VERDE FSST to the public. This document is available for viewing and downloading at *http://www.mesaverdeeis.com*. NMFS is a cooperating agency, as defined by the Council on Environmental Quality (40 CFR 1501.6), in the preparation of this EIS. Because NMFS is a cooperating agency, NMFS staff will be present at the associated public meetings to discuss NMFS' participation in the development of the EIS as well as the MMPA process. The dates and times of the public meetings may be viewed at: *http://www.mesaverdeeis.com*.

ESA

The Navy will be consulting with NMFS under section 7 of the ESA on this action. This consultation will be concluded prior to a determination on issuance regulations and an MMPA authorization to the Navy for this action.

Information Solicited

Interested persons may submit information, suggestions, and comments concerning the Navy's request (see **ADDRESSES**). All information, suggestions, and comments related to the Navy's FSST request and NMFS' potential development and implementation of regulations governing the incidental taking of marine mammals by the Navy in the Mayport, FL, area will be considered by NMFS in developing regulations governing the issuance of letters of authorization.

Dated: October 16, 2007.

Helen Golde,

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

[FR Doc. E7–21095 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN: 0648–XD62

Mid-Atlantic Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council's (Council) Summer Flounder Monitoring Committee, Scup Monitoring Committee, Black Sea Bass Monitoring Committee, and the Mid-Atlantic Fishery Council's and the Atlantic States Marine Fisheries Commission's Summer Flounder, Scup, and Black Sea Bass Advisors will hold public meetings.

DATES: The meetings will be held on Thursday, November 15, 2007 beginning at 10 a.m. with the Monitoring Committees. The Advisory Panels will begin meeting at 2 p.m. See **SUPPLEMENTARY INFORMATION** for meeting agenda.

ADDRESSES: The meetings will be held at the Renaissance Philadelphia Airport, 500 Stevens Drive, Philadelphia, PA 19113, telephone: (610) 521–5900.

Council address: Mid-Atlantic Fishery Management Council, Room 2115, 300 S. New Street, Dover, DE 19904; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Daniel T. Furlong, Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 674–2331, extension 19.

SUPPLEMENTARY INFORMATION: The purpose of these meetings is to recommend the 2008 recreational management measures for the summer flounder, scup, and black sea bass fisheries.

Although non-emergency issues not contained in this agenda may come before these groups for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Saunders, (302) 674–2331 extension 18, at the Council Office at least 5 days prior to the meeting date.

Dated: October 24, 2007.

Tracey L. Thompson,

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

[FR Doc. E7–21197 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC98

Vessel Monitoring Systems; Approval of Mobile Transceiver Unit

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

ACTION: Notice.

SUMMARY: This document provides notice of the type-approval of the Faria WatchDog 750VMS for use in the Northwestern Hawaiian Islands Marine National Monument.

ADDRESSES: To obtain copies of the list of NOAA-approved Vessel Monitoring Systems (VMS) Mobile Transceiver Unit and VMS Mobile Communications Service Providers, or to obtain information regarding the status of VMS systems being evaluated by NOAA, write to the VMS Support Center, NOAA Fisheries Service, Office for Law Enforcement (OLE), 8484 Georgia Avenue, Suite 415, Silver Spring, MD 20910; or call toll free 888–219–9228.

FOR FURTHER INFORMATION CONTACT: For questions regarding the status of VMS evaluations contact Jonathan Pinkerton, National VMS Program Manager by phone: 301–427–2300 or by fax: 301–427–2055.

SUPPLEMENTARY INFORMATION: The WatchDog 750VMS manufactured and sold by Faria WatchDog, Inc. has satisfied the requirements for type-approval for use in the Northwestern Hawaiian Islands Marine National Monument.

Faria WatchDog 750VMS

The transceiver consists of an integrated dual mode GPS/GSM/GPRS/Iridium Satellite Communicator mounted in the wheelhouse or on a console and antennas mounted atop the vessel. The MTU also includes a 7 inch color touch screen display that enables vessel operators to send and receive e-mail and electronic forms. The unit is pre-configured and tested for NOAA Fisheries Service VMS operations. Authorized dealers who are listed at *http://www.vmstracking.com* provide satellite commissioning services.

Automatic GPS position reporting starts after transceiver installation and power activation onboard the vessel. The unit is a car radio sized transceiver powered by any 9 to 16 VDC power supply. The unit can be factory configured for automatic reduced position transmissions when the vessel is stationary (i.e., in port) which allows for port stays in a reduced power state and without the need for unit shut down. The unit restarts normal position transmission automatically when the vessel goes to sea.

The unit has an omni-directional Iridium, GPS, and GSM/GPRS antennas, providing operation from 5 degrees above or below the horizon anywhere on earth. The GSM/GPRS capability gives the system the additional ability to communicate through the AT&T wireless network where available. Iridium only units are permitted for use in the Northwestern Hawaiian Islands Marine National Monument.

A configuration option is available to automatically send daily status reports to a private e-mail address. A 2 inch user interface is included with this system that displays if the MTU is operating properly and can send emergency notification messages to up to four e-mail addresses and/or telephone numbers. A complete list of options is available from the VMS provider.

A vessel owner may purchase the Faria Watchdog 750VMS and the Iridium/GSM communications service by contacting a Faria Watchdog Inc., authorized reseller. Reseller information can be found on the internet at *www.vmstracking.com*. Alternatively vessel owners may contact, Faria WatchDog Inc., 385 Norwich-New London Turnpike, Uncasville, CT 06382, 1–877–888–5569, 860 848 2704 fax, *information@fariawatchdog.com* e-mail. The owner should identify himself or herself as a vessel owner and identify which VMS required fishery they wish to participate in.

Dated: October 22, 2007.

William T. Hogarth,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. E7–21087 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD04

Vessel Monitoring Systems; Approved Mobile Transmitting Units for Use in the Fisheries off the West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery, Open Access Sector

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

ACTION: Notice of vessel monitoring systems; type–approval.

SUMMARY: This document provides notice of vessel monitoring systems (VMS) approved by NOAA for use by vessels participating in the Pacific Coast Groundfish Fishery, Open Access Sector and sets forth relevant features of the VMS.

ADDRESSES: To obtain copies of the list of NOAA–approved VMS mobile transmitting units and NOAA–approved VMS communications service providers, please contact the VMS Support Center at phone 888–219–9228, fax 301–427–0049, or write to NOAA Fisheries Office for Law Enforcement (OLE), VMS Support Center, 8484 Georgia Avenue, Suite 415, Silver Spring, MD 20910. For more addresses regarding approved VMS, see the **SUPPLEMENTARY INFORMATION** section, under the heading VMS Provider Address.

FOR FURTHER INFORMATION CONTACT: The public may acquire this notice, installation/activation checklists, and relevant updates by calling the VMS support center, phone 888–219–9228, fax 301–427–0049. For questions regarding the status of VMS provider evaluations, contact Jonathan Pinkerton, National VMS Program Manager, phone 301–427–2300; fax 301–427–0049. For questions regarding the Pacific Coast Groundfish Fishery, Open Access Sector VMS requirement, contact Joe Albert, Northwest Divisional VMS Program Manager, phone 206–526–6135.

SUPPLEMENTARY INFORMATION:

I. VMS Mobile Transceiver Units

A. BOATRACS – FMTC/G

The Boatracs satellite communications VMS transmitting units that meet the minimum technical requirements for the Pacific Coast Groundfish Fishery, Open Access Sector is the BOATRACS – FMTC/G. The address for the Boatracs distributor dealer contact is provided under the heading ''VMS Provider Address''.

The FMTC/G is an integrated GPS two–way satellite communications system, consisting of two major hardware components, the Mobile Communication Transceiver (MCT) and the Enhanced Display Unit (EDU). The MCT contains the antenna and integrated GPS which communicates with the satellite and contains the operating circuitry and memory. The EDU is a shock and splash resistant display and key board unit consisting of, a liquid crystal display, keyboard, with adjustable contrast, brightness, and audible alerts. A back light illuminates the display for night view. The EDU has message waiting, no signal, and audible message received indicators.

The Mobile Communications Transceiver is 6.7 inches high, 11.4 inches wide and weighs 11 pounds. The base of the unit is 6.595 inches in diameter. The MCT draws approximately 2.3 amps of current from the power supply while transmitting and 1.2 amps when vessel is idle.

The Enhanced Display Unit is a hardened and splash proof keyboard display unit with a 15–line X 40–character screen that allows for both text and graphics. It is 12.72 inches wide, 9.3 inches long, 2.21 inches in depth, and weighs 3 pounds and is holster mounted in the cabin.

A vessel owner may purchase this system by contacting the entity identified in this notice under the heading ''VMS Provider Address''. The owner should identify himself or herself as a vessel owner issued a permit to operate in the Pacific Coast Groundfish Fishery, Open Access Sector, so the transceiver set can be properly configured.

B. Faria WatchDog 750VMS with VTERM

The Faria WatchDog 750VMS with VTERM Features: The transceiver consists of an integrated dual model GPS/GSM/GPRS/Iridium Satellite Communicator mounted in the wheelhouse and antennas mounted atop the vessel. The Faria VTERM is a touch screen display provides the capability to process electronic forms, declarations, and send e–mail. A configuration option is available to automatically send daily status reports to a private e–mail address and position reports to a secure web site where the data is provided on a map and in tabular form. A 2–inch user interface is also included with this system that displays if the MTU is operating properly and can send emergency notification messages to up to four e–mail addresses and/or telephone numbers. The unit is pre–configured and tested for NMFS VMS (non–GMDSS) operations. Authorized dealers who are listed at *http://www.vmstracking.com* provide satellite commissioning services.

Automatic GPS position reporting starts after transceiver installation and power activation onboard the vessel. The unit is a car radio sized transceiver powered by any 9 to 16 VDC power supply. It is factory configured for automatic reduced position transmissions when the vessel is stationary (i.e., in port) which allows for port stays in a reduced power state and without the need for unit shut down. The unit restarts normal position transmission automatically when the vessel goes to sea.

The Faria WatchDog 750VMS has an omni–directional Iridium, GPS, and GSM/GPRS antennas, providing operation from +/− 5 degrees above or below the horizon anywhere on earth. The GSM/GPRS capability gives the system the additional ability to communicate through the Cingular wireless network where available.

A vessel owner may purchase this system by contacting the entity identified in this notice under the heading ''VMS Provider Address''. The owner should identify himself or herself as a vessel owner issued a permit to operate in the Pacific Coast Groundfish Fishery, Open Access Sector, so the transceiver set can be properly configured.

C. The Thrane & Thrane Sailor (TT–3026D) Gold VMS

The Thrane & Thrane Sailor Gold VMS(TT–3026D)have been found to meet the minimum technical requirements for vessels issued permits to operate in the Pacific Coast Groundfish Fishery, Open Access Sector. The address for the Thrane & Thrane distributor contact is provided in this notice under the heading VMS Provider Addresses.

The TT–3026D Gold VMS both feature an integrated GPS/Inmarsat-C unit. The unit is factory pre-configured for NMFS VMS operations (non-Global Maritime Distress & Safety System (non-GMDSS). The Thrane and Thrane Gold VMS includes a marine grade monitor with keyboard and integrated mouse. Satellite commissioning services are provided by Thrane & Thrane personnel.

Automatic GPS position reporting starts after transceiver installation and power activation onboard the vessel. The unit is an integrated transceiver/antenna/GPS design using a floating 10 to 32 VDC power supply. The unit is

configured for automatic reduced position transmissions when the vessel is stationary (i.e., in port). It allows for port stays without power drain or power shut down. The unit restarts normal position transmission automatically when the vessel goes to sea.

The TT–3026D provides operation down to +/-15 degree angles. The unit has the capability of two–way communications to send electronic forms and to receive e-mail and other messages. A configuration option is available to automatically send position reports to a private address, such as a fleet management company.

To use the TT–3026D the vessel owner will need to establish an Inmarsat-C system use contract with an approved Inmarsat-C communications service provider. The owner will be required to complete the Inmarsat-C Registration for Service Activation for Maritime Mobile Earth Station. The owner should consult with Thrane & Thrane when completing this form.

Thrane & Thrane personnel will perform the following services before shipment: (1) configure the transceiver according to OLE specifications for vessels issued permits to operate in the Pacific Coast Groundfish Fishery, Open Access Sector; (2) download the predetermined NMFS position reporting and broadcast command identification numbers into the unit; (3) test the unit to ensure operation when installation has been completed on the vessel; and (4) forward the Inmarsat service provider and the transceiver identifying information to OLE.

A vessel owner may purchase this system by contacting the entity identified in this notice under the heading ''VMS Provider Address''. The owner should identify himself or herself as a vessel owner issued a permit to operate in the Pacific Coast Groundfish Fishery, Open Access Sector, so the transceiver set can be properly configured.

II. Communications Service Providers

OLE has approved the below–listed communications service providers: Faria GSM/Iridium, Stratos Global, and VIZADA satellite communications services for the Pacific Coast Groundfish Fishery, Open Access Sector.

A. Qualcomm Satellite Service

Qualcomm Enterprise Services delivers integrated wireless applications and services to businesses around the world. We enable enterprises to operate at peak performance and improve the quality of life for customers in their value chain. Mobile workforce, enterprise management, and machine-to-machine communications are some of the key applications being mobilized by enterprises today.

Vessel owners wishing to use Qualcomm services will need to purchase a Boatracs FMTC/G transceiver. Information regarding configuration, installation, and service activation procedures for the transceiver can be obtained from Boatracs. The contact information for Boatracs is located under the heading of VMS provider addresses.

B. Faria GSM/Iridium Service

The Faria Watchdog GSM/Iridium Service is a dual mode GSM/GPRS and Iridium platform to ensure that connections are highly reliable, near real time and cost effective. The primary channel is the GSM/GPRS and the secondary channel is Iridium.

The owner must confirm the operation and communications service to ensure that position reports are automatically sent to and received by OLE before leaving on a fishing trip under VMS. OLE does not regard the fishing vessel as being in compliance until position reports are automatically received. For confirmation purposes, contact the VMS support center, phone 888–219–9228, fax 301–427–0049.

C. INMARSAT–C Communications Providers

It is recommended, for vendor warranty and customer service purposes, that the vessel owner keep for his or her records and that Stratos Global or VIZADA have on record the following identifying information: (a) Signed and dated receipts and contracts; (b) transceiver serial number; (c) VIZADA or Stratos Global customer number, user name and password; (d) e–mail address of transceiver; (e) Inmarsat identification number; (f) owner name; (g) vessel name; (h) vessel documentation or registration number; and (i) mobile earth station license (FCC license).

OLE will provide an installation and activation checklist which the vessel owner must follow. The vessel owner must sign a statement on the checklist certifying compliance with the installation procedures and return the checklist to OLE. Installation can be performed by an electronics specialist, and the installation cost is paid by the owner.

The owner must confirm the operation and communications service to ensure that position reports are automatically sent to and received by OLE before leaving on a fishing trip under VMS. OLE does not regard the fishing vessel as being in compliance until position reports are automatically received. For confirmation purposes, contact the VMS support center, phone 888–219–9228, fax 301–427–0049.

C1. Stratos Global

Stratos Global is a provider Vessel Monitoring Services to the fishing industry. By installing an approved OLE Imarsat–C transceiver on the vessel, fishermen can send and receive E–mail, to and from land, transceiver automatically sends vessel position reports to OLE, and is fully compliant with the International Coast Guard Search and Rescue Centers. Stratos Global Vessel Monitoring System Services are being sold through Thrane and Thrane Inc. For the Thrane and Thrane and Stratos Global addresses, look under the heading ''VMS Provider Address''.

C2. VIZADA Satellite Services

Inmarsat–C is a store–and–forward data messaging service. Inmarsat C allows users to send and receive information virtually anywhere in the world, on land, at sea, and in the air. Inmarsat–C supports a wide variety of applications including Internet e–mail, position and weather reporting, a free daily news service, and remote equipment monitoring and control. Mariners can use Inmarsat–C free of charge to send critical safety at sea messages as part of the U.S. Coast Guard's Automated Mutual–Assistance Vessel Rescue system and of the NOAA Shipboard Environmental Acquisition System programs. VIZADA Vessel Monitoring System Services is being sold through Thrane & Thrane, Inc. For the Thrane & Thrane and VIZADA addresses, look under the heading ''VMS Provider Address''.

VIZADA and Stratos Global Features offered through Thrane & Thrane: Customer Service supports the security and privacy of vessel accounts and messages with the following: (a) password authentication for vessel owners or agents and for OLE to prevent unauthorized changes or inquiries; and (b) separation of private messages from OLE messages. (OLE requires VMS–related position reports, only.) Billing is separated between accounts for the vessel owner and the OLE. VMS position reports and vessel–initiated messaging are paid for by the vessel owner. Messaging initiated from OLE operations center is paid for by NOAA.

Thrane & Thrane provides customer service for VIZADA and Stratos Global users to support and establish two–way transmission of transceiver unit configuration commands between the transceiver and land–based control

centers. This supports OLE's message needs and, optionally, fishermen's private message needs.

The vessel owner can configure automatic position reports to be sent to a private address, such as to a fleet management company. The vessel can send and receive private e–mail and other messages when the transceiver has such an input device as a laptop or personal computer attached.

Vessel owners wishing to use Stratos Global or VIZADA services will need to purchase an Inmarsat–C transceiver approved for the fishery. The owner will need to complete an Inmarsat–C system use contract with Stratos Global or VIZADA, including a mobile earth station license (FCC requirement). The transceiver will need to be commissioned with Inmarsat according to Stratos Global's or VIZADA instructions. The owner should refer to and follow the configuration, installation, and service activation procedures for the specific transceiver purchased.

III. VMS Provider Addresses

Boatracs corporate offices address is 9155 Brown Deer Rd, Suite 8, San Diego, CA 92121. Telephone numbers are toll free (877) 468–8722 and direct dialed (858) 458–8100. The primary point of contact is Debbie Foste, Manager of Fisheries, e–mail *dfoste@boatracs.com*, direct telephone number (877) 468–8722 ext. 105, and Winston Richardson, e–mail *wrichardson@boatracs.com*, direct telephone number (858) 458–8106.

Faria Watchdog Inc., authorized reseller. Reseller information can be found on the internet website at *www.vmstracking.com*. Alternatively vessel owners may contact, Faria WatchDog Inc., 385 Norwich–New London Turnpike, Uncasville, CT 06382, 1–877–888–5569, 860–848–2704 fax, *information@fariawatchdog.com* e–mail.

For Thrane & Thrane Sailor 3026D Gold VMS, Stratos Global or VIZADA information contact Lauri Paul, Marine Products, Thrane & Thrane, Inc., 509 Viking Drive, Suite K, L & M, Virginia Beach, VA 23452; voice: 757–753–9450 or 757–463–9557; fax: 757–463–9581, e–mail: *lp@thrane.com*; website: *http://www.us.thrane.com/*.

Dated: October 22, 2007.

William T. Hogarth,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. E7–21093 Filed 10–25–07; 8:45 am]

BILLING CODE 3510–22–S

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request: Part 41 Relating to Security Futures Products

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected costs and burden; it includes the actual data collection instruments [if any].

DATES: Comments must be submitted on or before November 26, 2007.

FOR FURTHER INFORMATION OR A COPY CONTACT: David Van Wagner, Commodity Futures Trading Commission, Division of Market Oversight, 202–418–5481, fax 202–418–5527, E-mail *dvanwagner@cftc.gov*, and refer to OMB Control No. 3038–0059.

SUPPLEMENTARY INFORMATION:

Title: Part 41 Relating to Security Futures Products (OMB Control No. 3038–0059). This is a request for extension of a currently approved information collection.

Abstract: Section 4d(c) of the Commodity Exchange Act (EAC), 7 U.S.C. 6d(c), requires the CFTC to consult with the SEC and issue such rules, regulations, or orders as are necessary to avoid duplicative or conflicting regulations applicable to firms that are fully registered with the SEC as brokers or dealers (broker-dealers) and the CFTC as futures commission merchants (FCMs) involving provisions of the CEA that pertain to the treatment of customer funds. The CFTC, jointly with the SEC, issued regulations requiring such dually-registered firms to make choices as to how its customers' transactions in security futures products (SFP) will be treated, either as securities transactions held in a securities account or as futures transactions held in a futures account. How an account is treated is important in the unlikely event of the insolvency of the firm. Only securities accounts receive insurance protection under provisions of the Securities Investor Protection Act. By contrast, only futures accounts are subject to the protections provided by the segregation requirements of the CEA.

As 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 the CFTC's regulations were published on December 30, 1981. See 46 FR 63035 (Dec. 30, 1981). The **Federal Register** notice with a 60-day comment period soliciting comments on this collection of information was published on August 21, 2007 (72 FR 46613).

Burden Statement: The respondent burden for this collection is estimated to average .59 hours per response. These estimates include 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; and transmit or otherwise disclose the information.

Respondents/Affected Entities: 144.

Estimated number of responses: 2,739.

Estimated total annual burden on respondents: 1,620.48 hours.

Frequency of collection: On occasion.

Send comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, to the addresses listed below. Please refer to OMB Control No. 3038–0059 in any correspondence.

David Van Wagner, Chief Counsel, Division of Market Oversight, U.S. Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581, and Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for CFTC, 725 17th Street, Washington, DC 20503.

Dated: October 22, 2007.

David A. Stawick,

Secretary of the Commission.

PART 41—SECURITY FUTURES PRODUCTS OMB COLLECTION NO. 3038–0059

	Estimated Number of respondents or recordkeepers per year	Reports annually by each respondent	Total annual responses	Estimated average number of hours per response	Estimated total number of hours of annual burden in fiscal year
Reporting:					
41.3 Application for exemption by intermediaries ..	5	1	5	25,000	125
41.23(a)(1)–(5) Listing of SFPs	3	20	60	4	240
41.23(a)(6) and 41.24(a)(5)	3	25	75	.033	2.48
41.25(a)(1) Reporting of data	3	20	60	1	60
41.27(c) Rules prohibiting exemptions	1	1	1	4	4
41.27(e) Rules permitting exemptions	1	1	1	4	4
41.31 SFPCM designation (one time only)	1	1	1	5	5
41.32 SFPCM continuing obligations	3	20	60	4	240
41.33 Application for exemption by SFPCM	1	1	1	40	40
41.41 FCM/B–D disclosure	60	40	2,400	.25	600
41.49 Margin rule changes	3	5	15	4	60
Subtotal Reporting Requirements	84	.....	2,679	.....	1,380.48
Recordkeeping:					
41.41(a)(2) Handling of customer accounts	60	1	60	4	240
Subtotal Recordkeeping Requirements	60	1	60	4	240
Total Reporting and Recordkeeping	144	.....	2,739	0.592	1,620.48

[FR Doc. 07–5301 Filed 10–25–07; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the Defense Department Advisory Committee on Women in the Services (DACOWITS)

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a), Public Law 92–463, as amended, notice is hereby given of a forthcoming meeting of the Defense Department Advisory Committee on Women in the Services (DACOWITS). The purpose of the Committee meeting is to do the second review of the 2007 report and work on the findings and recommendations. The meeting is open to the public, subject to the availability of space.

Interested persons may submit a written statement for consideration by the Defense Department Advisory Committee on Women in the Services. Individuals submitting a written statement must submit their statement to the Point of Contact listed below at the address detailed below, NLT 5 p.m., 12 November 2007. If a written statement is not received by 12 November 2007 prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the Defense Department Advisory Committee on Women in the Services until its next open meeting. The Designated Federal Officer will review all timely submissions with the Defense Department Advisory Committee on Women in the Services Chairperson and ensure they are provided to the members of the Defense Department Advisory Committee on Women in the Services. If members of the public are interested in making an oral statement, a written statement must be submitted as above. After reviewing the written comments, the Chairperson and the Designated Federal Officer will determine who of the requesting persons will be able to make an oral presentation of their issue during an open portion of this meeting or at a future meeting. Determination of who will be making an oral presentation will depend on time available and if the topics are relevant to the Committee's activities. Two minutes will be allotted to persons desiring to make an oral presentation. Oral presentations by members of the public will be permitted only on Thursday, 15 November from 4:30 p.m. to 5 p.m. before the full Committee. Number of oral presentations to be made will depend on the number of requests received from members of the public.

DATES: 15 November 2007, 8:30 a.m.–5 p.m., 16 November 2007, 8:30 a.m.–5 p.m.

Location: Double Tree Hotel Crystal City National Airport, 300 Army Navy Drive, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: MSgt Robert Bowling, USAF, DACOWITS, 4000 Defense Pentagon, Room 2C548A, Washington, DC 20301–4000. *Robert.bowling@osd.mil* Telephone (703) 697–2122. Fax (703) 614–6233.

SUPPLEMENTARY INFORMATION: Meeting agenda.

Thursday, 15 November 2007 8:30–5 p.m.

Welcome & Administrative Remarks.

Review second draft of the report.

Work on findings and recommendations.

Discuss topics for next year.

Public Forum.

Friday, 16 November 2007 8:30 a.m.–5 p.m.

Welcome & Administrative Remarks.

Review second draft of the report.

Work on findings and recommendations.

Note: Exact order may vary.

Dated: October 22, 2007.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

[FR Doc. 07–5303 Filed 10–25–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Availability of the Final Environmental Impact Statement (FEIS) for the 2005 Base Realignment and Closure (BRAC) and Transformation Actions at Fort Benning, GA

AGENCY: Department of the Army, DoD

ACTION: Notice of availability (NOA).

SUMMARY: The Department of the Army announces the availability of the FEIS which evaluates the potential environmental and socioeconomic impacts associated with the BRAC and Transformation Actions at Fort Benning, Georgia.

DATES: The waiting period for the FEIS will end 30 days after publication of an NOA in the **Federal Register** by the U.S. Environmental Protection Agency.

ADDRESSES: To obtain a copy of the FEIS contact Mr. John Brent, Fort Benning Directorate of Public Works, Environmental Management Division, Bldg #6 (Meloy Hall), Room 310, Fort Benning, GA 31905; e-mails to *john.brent@benning.army.mil*.

FOR FURTHER INFORMATION CONTACT: Ms. Monica Manganaro at (706) 545–3438, Fort Benning Public Affairs Office or Mr. Brandon Cockrell at (706) 545–3210.

SUPPLEMENTARY INFORMATION: The FEIS covers the construction activities, personnel increases, and training activities associated with the BRAC Commission recommendations, the Global Defense Posture Realignment (GDPR) overseas restationing actions, Army Modular Force (AMF) initiatives, and other discretionary stationing activities at Fort Benning, Georgia.

As a result of BRAC recommendations, Fort Benning will be receiving personnel, equipment, and missions from various realignment and closure actions within the Department of Defense. To implement the BRAC Commission recommended initiatives, the Army will provide the necessary facilities/buildings and infrastructure to support the changes. Permanent facilities will be constructed to house the Armor Center and School as well as several other unit relocations. Fort Benning also proposes to implement other transformation actions as the Army undergoes restructuring to meet the demands of the 21st century. The AMF initiative involves the Army's transition from a division-centric design to a standard brigade organization. The reshaping of the military force structure also includes provision for the return of units currently based overseas to United States installations as part of the GDPR. Finally, discretionary stationing actions (activations, inactivations, realignments, and relocations) are proposed, which contribute to and are interrelated with the transformation process.

Following an examination of all implementation alternatives, those alternatives found not to be viable were dropped from further analysis in the Fort Benning FEIS. Alternatives carried forward are: (1) Transformation Alternative A, which entails cantonment area development, construction of small- and large-caliber weapons ranges, heavy maneuver areas and corridors, a driver's training course, off-road driver's training area, and a vehicle recovery area to support the training range requirements; (2) Transformation Alternative B (the Army's Preferred Alternative), which is similar to Transformation Alternative A, with cantonment, maneuver and range projects, but with additional development of new tank training areas in the Good Hope area in the southern part of Fort Benning; and (3) the No Action Alternative, under which Fort Benning missions would continue as they were being performed in November 2005, when the BRAC Commission recommendations became law. The No Action Alternative provides the environmental baseline conditions for comparison to the impacts associated with the action alternatives.

Environmental consequences of two action alternatives (Alternative A and the Preferred Alternative), as well as the No Action Alternative, were evaluated for 13 resources. Under Alternative A, approximately 10,700 acres would be disturbed by Transformation activities; under the Preferred Alternative, approximately 19,100 acres would be disturbed. With the Preferred Alternative, there could potentially be land use compatibility issues for lands adjacent to the proposed Good Hope Maneuver Area. Changes would occur to aesthetic and visual resources, but impacts would not be significant. In terms of socioeconomics, development would take place and personnel growth would result in economic gains under both action alternatives, although the majority of the regional population increase is due to non-Army, private sector decisions; housing would be required; and if the local market could not support this increase in needs, there could be minor short-term effects. The Army and the local community are planning and coordinating to accommodate the increased student population. One available funding source for additional school construction is the Qualified Public Educational Facility (QPEF) Bond Program. On-post traffic congestion both during the construction period and operational phase is anticipated as well as traffic buildup at the main gate during peak hours; however, these would not be to such an extent to be significant with implementation of mitigation measures. Air quality would experience short-term construction emissions increases but would not significantly affect regional air quality in the long term. Noise would increase both on and off post, increasing the potential for annoyance in adjacent communities, but would not be significant with implementation of existing complaint processes. Utilities, safety, cultural resources, and hazardous and toxic materials and waste would not be significantly impacted by the proposed action. However, soils, water resources (including wetlands and state designated impaired streams), special status species (particularly, a population of relict trillium and the Rd-cockaded woodpecker), and Unique Ecological Areas could experience significant impacts under either action alternative. Cumulative impacts are expected to be the same for both action alternatives and would add significant impacts for socioeconomics given the anticipated additional Army and private growth in the area.

Fort Benning proposes to mitigate significant negative effects through a variety of strategies, including avoiding sensitive cultural resource sites, and preparation of an operational noise plan among others. Implementing applicable road improvements on post could minimize significant impacts to increased traffic. Through formal consultation with U.S. Fish and Wildlife Service, plans to minimize the effects on federally listed species will also be implemented, as specified in a biological assessment and opinion.

A Record of Decision will be signed at the end of the 30-day waiting period.

An electronic version of the FEIS can be viewed or downloaded from the following Web site: *http://www.hqda.army.mil/acsim/brac/nepa_eis_docs.htm*.

Dated: October 18, 2007.

Addison D. Davis, IV,

Deputy Assistant Secretary of the Army, (Environment, Safety and Occupational Health).

[FR Doc. 07–5250 Filed 10–25–07; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF ENERGY

Office of Science; DOE/Advanced Scientific Computing Advisory Committee

AGENCY: Department of Energy.

ACTION: Notice of opening meeting.

SUMMARY: This notice announces a meeting of the Advanced Scientific Computing Advisory Committee (ASCAC). Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Tuesday, November 6, 2007, 9 a.m. to 5:30 p.m.; Wednesday, November 7, 2007, 9 a.m. to 11:45 a.m.

ADDRESSES: Hilton Gaithersburg, 620 Perry Parkway, Gaithersburg, MD 20877.

FOR FURTHER INFORMATION CONTACT: Melea Baker, Office of Advanced Scientific Computing Research; SC–21/Germantown Building; U.S. Department of Energy; 1000 Independence Avenue, SW.; Washington, DC 20585–1290; Telephone (301) 903–7486, (E-mail: *Melea.Baker@science.doe.gov).*

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: The purpose of this meeting is to provide advice and guidance with respect to the advanced scientific computing research program.

Tentative Agenda: Agenda will include discussions of the following:

Tuesday, November 6, 2007

Opening Remarks from the Committee Chair.
View from Washington and Germantown.
Update on SciDAC.
Quantum Simulations of Materials and Nanostructure (Q–SIMAN).
Fusion Simulation Project.
New Charge—ASCR Role in the Fusions Simulation Project (FSP).
The Role of High Performance Computing (HPC) in the Office of Science.
Report Discussion on Charge—Networking.
Report Discussion on Charge—Joint Panel with BERAC on Life Sciences Goal (GTL).
Report Discussion on Charge—Joint Panel with BERAC on Climate.
Public Comment.

Wednesday, November 7, 2007

Applied Math Update.
Applied Mathematics Strategic Planning.
Pioneer Applications at the Leadership Class Facility (LCF).
New Charge—Committee of Visitors.
Public Comment.

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Melea Baker via FAX at 301–903–4846 or via e-mail *Melea.Baker@science.doe.gov*. You must make your request for an oral statement at least 5 business days prior to the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule. This notice is being published less than 15 days before the date of the meeting due to programmatic issues.

Minutes: The minutes of this meeting will be available for public review and copying within 30 days at the Freedom of Information Public Reading Room; 1E–190, Forrestal Building; 1000 Independence Avenue, SW.; Washington, DC 20585; between 9 a.m. and 4 p.m., Monday through Friday, except holidays.

Issued in Washington, DC on October 22, 2007.

Rachel Samuel,

Deputy Committee Management Officer.

[FR Doc. 07–5315 Filed 10–25–07; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR08–2–000]

Acacia Natural Gas Corporation; Notice of Petition for Rate Approval

October 18, 2007.

Take notice that on October 12, 2007, Acacia Natural Gas Corporation (Acacia) filed a petition for rate approval for NGPA section 311 maximum interruptible transportation rates equal to 12.23 cents per MMBtu, pursuant to section 284.123(b)(2) of the Commission's regulations, with a proposed effective date of January 1, 2008.

Any person desiring to participate in this rate proceeding must file a motion to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. October 31, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21150 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER07–1175–001]

Ameren Illinois Transmission Company; Notice of Filing

October 18, 2007.

Take notice that on October 3, 2007, pursuant to the Federal Energy Regulatory Commission's September 17, 2007, letter order, Ameren Illinois Transmission Company (Ameren Transco) filed a certificate of concurrence Ameren Transco designating the Joint Ownership Agreement, accepted as Rate Schedule No. 1.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on October 31, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21154 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ID–4025–001]

Brown, D. Tim; Notice of Filing

October 18, 2007.

Take notice that on October 15, 2007, Tim D. Brown filed an application for approval to hold interlocking positions, pursuant to section 45.8 of the Commission's regulation, 18 CFR 45.8 (2007).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all the parties in this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on November 14, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21155 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL08–4–000]

Entergy Gulf States, Inc.; Notice of Filing

October 18, 2007.

Take notice that on October 12, 2007, Entergy Gulf States, Inc., on behalf of Gulf States Louisiana, L.L.C. and Entergy Texas, Inc., filed a petition for declaratory order regarding payment of dividends from paid-in capital.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on November 2, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21153 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–6–000 and Docket No. PF07–4–000]

Midcontinent Express Pipeline LLC; Notice of Application

October 23, 2007.

Take notice that on October 9, 2007, and supplemented on October 19, 2007, Midcontinent Express Pipeline LLC (Midcontinent), 747 East 22nd Street, Lombard, Illinois 60148, filed an abbreviated application pursuant to section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations, for a certificate of public convenience and necessity to construct and operate a new 502-mile natural gas pipeline system from southeastern

Oklahoma to western Alabama. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Midcontinent requests: (1) Authorization to construct a new natural gas pipeline system consisting of 502 miles of primarily 30-inch to 42-inch diameter pipeline, a booster compressor station (9,470 hp), and 4 mainline compressor stations (102,250 hp), which will originate in southeastern Oklahoma, continue through Texas, Louisiana, Mississippi, and terminate in western Alabama; (2) authorization to lease up to 800,000 Dth/d in the Enogex Inc. intrastate system in Oklahoma to be connected at the origin of the Midcontinent system; (3) approval of Midcontinent's pro forma tariff and proposed recourse rates; and (4) issuance of a blanket construction certificate pursuant to Subpart F of Part 157 and a blanket transportation certificate pursuant to Subpart G of Part 284. On October 9, 2007, Enogex Inc. filed a related application, in Docket No. CP08–9–000, seeking a limited-jurisdiction certificate authorizing Enogex to lease up to 800,000 Dth/d of its intrastate pipeline capacity to Midcontinent.

Midcontinent proposes phased in-service dates and recourse rates. Midcontinent has committed to lease 275,334 Dth/d of capacity on the Enogex system but requests authority to increase the lease capacity up to 800,000 Dth/d at any time during the first 5 years after the project's in-service date. Midcontinent also requests that it be allowed up to 5 years after the project's in-service date in which to construct 2 of the requested mainline compressor stations. The project will have two zones. Without the 2 delayed-construction compressor stations, Zone 1 will have a capacity of 1,400,000 Dth/d and Zone 2 capacity will be 1,000,000 Dth/d. Construction of the final 2 compressor stations will provide an additional 100,000 Dth/d of capacity in Zone 1 and an additional 200,000 Dth/d in Zone 2. Estimated initial project cost is $1.28 billion without the final 2 compressor stations, rising to $1.34 billion with the final 2 compressor stations. Midcontinent requests a preliminary determination on non-environmental issues by March 2008, and a final order by July 2008, in order to commence construction by August 1, 2008. Midcontinent anticipates placing some pipeline facilities in-service on October 31, 2008, with all of the proposed facilities, except the final 2 compressor stations, going into service on February 28, 2009.

Any questions regarding the application are to be directed to Bruce H. Newsome, Vice President, Regulatory, Midcontinent Express Pipeline LLC, 747 East 22nd Street, Lombard, Illinois 60148–5072, telephone: (630) 691–3526 or e-mail: *bruce_newsome@kindermorgan.com*.

On February 22, 2007, the Commission staff granted Midcontinent's request to utilize the National Environmental Policy Act (NEPA) Pre-Filing Process and assigned Docket No. PF07–4–000 to staff activities involving the project. Now, as of the filing of this application on October 9, 2007, the NEPA Pre-Filing Process for this project has ended. From this time forward, this proceeding will be conducted in Docket No. CP08–6–000, as noted in the caption of this notice.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

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 encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit the original and 14 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street, NE., Washington, DC 20426.

Comment Date: November 13, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21229 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF07–3011–000]

Southeastern Power Administration; Notice of Filing

October 18, 2007.

Take notice that on September 13, 2007, the Deputy Secretary, U.S. Department of Energy, pursuant to the authority vested in the Deputy Secretary by the Department of Energy's Delegation Order Nos. 00–001.00C and 00–037.00, and by sections 302(a) and 301(b) of the Department of Energy Organization Act (Pub. L. 95091), submitted for confirmation and approval on a final basis, Rate Schedules SOCO–1–C, SOCO–2–C, SOCO–3–C, SOCO–4–C, ALA–1–L, MISS–1–L, Duke-1–C, Duke-2–C, Duke-3–C, Duke-4–C, Santee-1–C, Santee-2–C, Santee-3–C, Santee-4–C, SCE&G–1–C, SCE&G–2–C, SCE&G–3–C, SCE&G–4–C, Pump-1–A, Pump-2, Replacement-1, and Regulation-1, effective October 1, 2007 and ending September 30, 2012.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on November 19, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21158 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RC08–1–000]

Southeastern Power Administration; Notice of Filing

October 19, 2007.

Take notice that on October 15, 2007, Southeastern Power Administration (Southeastern) filed an appeal of the September 25, 2007 decision of the North American Electric Reliability Corporation (NERC) to include Southeastern Power Administration on the NERC compliance registry within the SERC Reliability Corporation for the function of transmission operator and resource planner. Southeastern states that it has the responsibility to market the electric power generated at reservoir projects owned and operated by the U.S. Army Corps of Engineers in the southeast and neither owns or operates a generation or transmission system. Southeastern asks the Commission to reverse the NERC's decision to register Southeastern as a transmission operator and resource planner.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on November 14, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21159 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–5–000]

Southern Natural Gas Company; Magnolia Enterprise Holdings, Inc.; Notice of Application

October 19, 2007.

Take notice that on October 5, 2007, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, Alabama 35202–2563, filed an application in Docket No. CP08–5–000 pursuant to section 7 of the Natural Gas Act (NGA), for approval to abandon and lease certain pipeline and appurtenant facilities and authorization to construct, install and operate a new compressor unit on its Cypress Pipeline and related appurtenant facilities. Magnolia Enterprise Holdings, Inc. (MEHI), Ten Peachtree Place, Location 1466, Atlanta, Georgia 30309, filed a request in the same application pursuant to section 7 of the NGA, for authorization to acquire certain pipeline, measurement and compression facilities and to lease those facilities back to Southern, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that pursuant to the terms of a Purchase and Sale Agreement between Southern and AGL Resources, Inc., MEHI's parent company, Southern requests authorization to abandon by sale to MEHI an undivided interest of the following:

Twin 30 Pipelines extending from Southern's interconnection with Elba Island to Port Wentworth, Georgia in Chatham

County, Georgia and Jasper County, South Carolina; 10 miles of Southern's 20-inch Wrens to Savannah Second Loop Line from the interconnection with the Twin 30 Pipelines at Port Wentworth, Georgia, to the Rincon Gate in Effingham County, Georgia; The Cypress Pipeline from the take off point on the Wrens Savannah Lines to the interconnection with Atlanta Gas Light Company's (AGLC) Brunswick Pipeline in Glynn County, Georgia, including, as applicable, the compressor facilities to be constructed on that portion of the Cypress Pipeline; and Southern's Brunswick Pipeline from the Jackson Measurement Station at Milepost 53.8 to Milepost 0.0.

It is stated that upon closing of the sale of the facilities, MEHI and Southern request authorization for MEHI to lease to Southern the facilities, including the compression facilities to be constructed, and AGLC's Brunswick Pipeline that it proposes to sell to MEHI so that Southern may operate and maintain the facilities as part of its interstate gas pipeline system under the terms of Southern's tariff. In addition, it is stated that MEHI requests pregranted abandonment authority to sell the AGLC Brunswick Pipeline back to AGLC upon termination of the lease.

This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or Telephone: 202–502–6652; Toll-free: 1–866–208–3676; or for TTY, contact (202) 502–8659.

Any initial questions regarding Southern's proposal in this application should be directed to Patricia S. Francis, Senior Counsel, Southern Natural Gas Company, P.O. Box 2563, Birmingham, Alabama 35202–2563, or call (205) 325–7696. Any initial questions regarding EMHI's proposal in this application should be directed to Shannon Omia Pierce, Senior Regulatory Counsel, AGL Resources, Inc., Ten Peachtree Place, 15th floor, Atlanta, Georgia 30309, or call (404) 584–3394.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceeding for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene 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 commentors 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 commentors will not be required to serve copies of filed documents on all other parties. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the applicant. However, the non-party commentors 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 strongly encourages electronic filings of comments, protests, and interventions via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Comment Date: November 9, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21160 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF07–4021–000]

Southwestern Power Administration; Notice of Filing

October 18, 2007.

Take notice that on September 17, 2007, the Deputy Secretary, U.S. Department of Energy, pursuant to the authority vested on the Deputy Secretary by the Department of Energy's Delegation Order Nos. 00–001.00C and 00–037.00, and by sections 301(b), 302(a), 402(e), 641, 642, 643 and 644 of the Department of Energy Organization Act (Pub. L. 95091), submitted for confirmation and approval on a final basis, the annual power rate increase for the sale of power and energy by the Southwestern Power Administration from the Sam Rayburn Dam to the Sam Rayburn Dam Electric Cooperative, Inc., under Contract No. DE–PM–75–92SW00215, effective October 1, 2007 and ending September 30, 2012.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). 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 notice of intervention or motion to intervene, as

appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on November 19, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21151 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–10–000]

Trunkline Gas Company, LLC; Notice of Request Under Blanket Authorization

October 19, 2007.

Take notice that on October 16, 2007, Trunkline Gas Company LLC (Trunkline), P. O. Box 4967, Houston, Texas 77210–4967, filed in Docket No. CP08–10–000 a prior notice request pursuant to sections 157.205(b), 157.208(c), and 157.212 of the Commission's regulations under the Natural Gas Act (NGA), and Trunkline's blanket certificate issued in Docket No. CP83–84–000 on October 1, 1983.[1] Trunkline seeks authorization to construct, own, and operate a new receipt point to receive revaporized liquefied natural (LNG)gas in Beauregard Parish, Louisiana, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Specifically, Trunkline proposes design and construct two 24-inch tap assemblies, valves, overpressure protection equipment, a remote terminal unit and approximately 400 feet of 24-inch pipe to receive LNG from Creole Trail LNG, L.P. LNG import terminal by way of the Cheniere Pipeline facilities.[2]

Any questions regarding this application should be directed to Stephen T. Veatch, Regulatory Affairs, Trunkline Gas Company, LLC, 5444 Westheimer Road, Houston, TX, 77056, or call (713)989–2024 or (713)989–7660.

Any person or the Commission's Staff may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and, pursuant to section 157.205 of the Commission's Regulations under the Natural Gas Act (NGA) (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the Internet in lieu of paper. See 18 CFR 385.2001(a) (1) (iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

Comment Date: December, 18, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21162 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

[1] 22 FERC ¶ 62,044 (1983).

[2] *See Creole Trail LNG, L.P., et al.*, 115 FERC ¶ 61,331 (2006).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP08–27–000]

Southern California Generation Coalition, Complainant, v. Southern California Gas Company, Respondent; Notice of Complaint

October 23, 2007.

Take notice that on October 22, 2007, the Southern California Generation Coalition (SCGC) filed a formal complaint against Southern California Gas Company (SoCalGas) pursuant to section 5 of the Natural Gas Act (NGA), 15 U.S.C. 171d, and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206. SCGC alleges that SoCalGas has received California Public Utilities Commission (CPUC) approval to charge and, absent Commission intervention, will charge and intrastate fee for access to its intrastate pipeline system in violation of the Supremacy Clause of the United States Constitution, the NGA, the Commission's rules and regulations and under the NGA, and Commission precedent.

SCGC certifies that copies of the complaint were served on counsel for SoCalGas as listed in the CPUC proceeding because SoCalGas is not listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). 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 notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the

''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on November 13, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21228 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

October 23, 2007.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC08–8–000.

Applicants: Consolidated Water Power Company; NewPage Energy Services, LLC; Stora Enso Oyj, Stora Enso North America, Inc.; Stora Enso North America Corp.; NewPage Group, Inc; NewPage Holding Corporation; NewPage Corporation.

Description: The NewPage Companies submits a joint application for authorization under Section 203 of the Federal Power Act.

Filed Date: 10/17/2007.

Accession Number: 20071018–0196.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 7, 2007.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG08–9–000.

Applicants: Wharton County Generation, LLC.

Description: Wharton County Notice of Self-Certification of EWG Status.

Filed Date: 10/19/2007.

Accession Number: 20071019–5096.

Comment Date: 5 p.m. Eastern Time on Friday, November 9, 2007.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER97–420–015.

Applicants: ProLiance Energy, LLC.

Description: ProLiance Energy, LLC submits a change in status notification.

Filed Date: 10/16/2007.

Accession Number: 20071018–0081.

Comment Date: 5 p.m. Eastern Time on Tuesday, November 6, 2007.

Docket Numbers: ER04–157–024; ER04–714–014.

Applicants: Bangor Hydro-Electric Company; Florida Power & Light Company New England.

Description: Fitchburg Gas & Electric Light Company Revised Refund Report Pursuant to FERC Order Dated July 26, 2007.

Filed Date: 10/18/2007.

Accession Number: 20071018–5057.

Comment Date: 5 p.m. Eastern Time on Thursday, November 8, 2007.

Docket Numbers: ER07–1022–002.

Applicants: Duke Energy Carolinas, LLC.

Description: Duke Energy Carolinas, LLC. submits Substitute Original Sheet 4 to FERC Electric Tariff, Fifth Revised Volume 3 *et al.* to be effective 9/18/07.

Filed Date: 10/17/2007.

Accession Number: 20071018–0080.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 7, 2007.

Docket Numbers: ER07–1201–001.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool Inc submits Exhibit I a partially executed Network Integration Transmission Service Agreement with Transmission Provider and American Electric Power Service Corporation.

Filed Date: 10/18/2007.

Accession Number: 20071019–0036.

Comment Date: 5 p.m. Eastern Time on Thursday, November 8, 2007.

Docket Numbers: ER07–1205–001.

Applicants: PJM Interconnection, LLC.

Description: PJM Interconnection, LLC responds to FERC's 9/21/07 deficiency letter re their 7/26/07 filing of an executed interconnection service agreement with WM Renewable Energy, LLC.

Filed Date: 10/22/2007.

Accession Number: 20071023–0034.

Comment Date: 5 p.m. Eastern Time on Tuesday, November 13, 2007.

Docket Numbers: ER07–1247–002.

Applicants: FC Energy Services Company, LLC.

Description: FC Energy Services Company, LLC submits an amendment to its proposed market based rate tariff, entitled FERC Electric Tariff 1.

Filed Date: 10/19/2007.

Accession Number: 20071022–0087.

Comment Date: 5 p.m. Eastern Time on Friday, November 9, 2007.

Docket Numbers: ER07–1258–002.

Applicants: Rocky Mountain Power, LLC.

Description: Rocky Mountain Power, LLC submits Substitute Original Sheet 1 and Second Substitute Original Sheet 2 to its revised tariff to delete the following provisions prohibition on affiliate sales, etc.

Filed Date: 10/22/2007.

Accession Number: 20071023–0033.

Comment Date: 5 p.m. Eastern Time on Tuesday, November 13, 2007.

Docket Numbers: ER07–1259–002.

Applicants: San Joaquin Cogen, LLC.

Description: San Joaquin Cogen, LLC submits its Second Substitute Original Sheet 1–3 to its FERC Electric Tariff, First Revised Volume 1, etc.

Filed Date: 10/22/2007.

Accession Number: 20071023–0031.

Comment Date: 5 p.m. Eastern Time on Tuesday, November 13, 2007.

Docket Numbers: ER07–1268–001.

Applicants: PacifiCorp.

Description: PacifiCorp submits Exhibits A and B two supplements to the 10/1/98 Facilities Agreement with Southern Utah Power Systems, *et al.*

Filed Date: 10/18/2007.

Accession Number: 20071022–0089.

Comment Date: 5 p.m. Eastern Time on Thursday, November 8, 2007.

Docket Numbers: ER07–1309–001.

Applicants: Dynegy Oakland, LLC.

Description: Dynegy Oakland, LLC. submits revised tariff sheets to its Reliability Must-Run Agreement with the California ISO.

Filed Date: 10/17/2007.

Accession Number: 20071019–0039.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 7, 2007.

Docket Numbers: ER07–1317–001.

Applicants: Citizens Electric Company of Lewisburg, PA.

Description: Citizens' Electric Co. of Lewisburg, PA submits a Supplement to the Petition for Acceptance of Initial Tariff, Waivers and Blanket Authority.

Filed Date: 10/17/2007.

Accession Number: 20071018–0079.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 7, 2007.

Docket Numbers: ER07–1331–002.

Applicants: Indianapolis Power & Light Company.

Description: Indianapolis Power & Light Company submits the corrected designation of First Revised Rate Schedule 21; Original Sheet 1 through 11.

Filed Date: 10/19/2007.

Accession Number: 20071023–0032.

Comment Date: 5 p.m. Eastern Time on Friday, November 9, 2007.

Docket Numbers: ER07–1341–002.

Applicants: York Generation Company, LLC.

Description: York Generation Company, LLC supplements the notice of succession filed on 9/4/07 & supplemented 10/1/07, etc.

Filed Date: 10/19/2007.

Accession Number: 20071022–0088.

Comment Date: 5 p.m. Eastern Time on Friday, November 9, 2007.

Docket Numbers: ER07–1382–001.

Applicants: Duke Energy Carolinas, LLC.

Description: Duke Energy Carolinas, LLC.submits an errata to its filing of a non-firm Transmission Service Agreement with Cargill Power Markets, LLC.

Filed Date: 10/17/2007.

Accession Number: 20071019–0038.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 7, 2007.

Docket Numbers: ER08–1–001.

Applicants: Yuma Power Limited Liability Company.

Description: Yuma Power Limited Liability Co submits its proposed Rate Schedule No. 1, revised Original Sheet no. 2 on 10/3/07 and 10/16/07 its 10/1/07 and this filing.

Filed Date: 10/03/2007; 10/16/2007.

Accession Number: 20071003–0229; 20071018–0083.

Comment Date: 5 p.m. Eastern Time on Monday, October 29, 2007.

Docket Numbers: ER08–65–000.

Applicants: Westar Energy, Inc.

Description: Westar Energy, Inc. submits a Notice of Cancellation of a Generating Municipal Electric Service Agreement with the City of Girard, Kansas.

Filed Date: 10/17/2007.

Accession Number: 20071018–0082.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 7, 2007.

Docket Numbers: ER08–67–000.

Applicants: Ameren Services Company.

Description: Ameren Services Co et al submit an executed service agreement fore Wholesale Distribution Service with the City of Farmington, Missouri.

Filed Date: 10/17/2007.

Accession Number: 20071019–0037.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 7, 2007.

Docket Numbers: ER08–69–000.

Applicants: ISO New England, Inc.

Description: ISO New England, Inc., *et al.* jointly submits its revised tariff sheets & supporting testimony of Hung-po Chao, the Director of the ISO's Internal Market Monitoring Unit, reflecting proposed revisions to Market Rule 1.

Filed Date: 10/18/2007.

Accession Number: 20071022–0091.

Comment Date: 5 p.m. Eastern Time on Thursday, November 8, 2007.

Docket Numbers: ER08–70–000.

Applicants: FirstEnergy Service Company.

Description: FirstEnergy Services Company et al submits its Notice of Cancellation of Appendix 8 to Schedule E of the Central Area Power Coordinating Group Basic Operating Agreement.

Filed Date: 10/18/2007.

Accession Number: 20071022–0092.

Comment Date: 5 p.m. Eastern Time on Thursday, November 8, 2007.

Docket Numbers: ER08–71–000; ER08–72–000.

Applicants: Powerex Corporation and Northwestern Corporation

Description: Powerex Corp et al submits an executed Agreement for Regulating Reserve Services.

Filed Date: 10/18/2007.

Accession Number: 20071022–0093.

Comment Date: 5 p.m. Eastern Time on Thursday, November 8, 2007.

Docket Numbers: ER08–73–000.

Applicants: California Independent System Operator Corporation

Description: California ISO submits proposed amendments to its FERC Electric Tariff to implement its Market Redesign and Technology Upgrade.

Filed Date: 10/19/2007.

Accession Number: 20071023–0030.

Comment Date: 5 p.m. Eastern Time on Friday, November 9, 2007.

Docket Numbers: ER08–74–000.

Applicants: North American Energy Credit and Clearing.

Description: North American Energy Credit and Clearing—Finance ,LLC. submits its petition for acceptance of initial rate tariff, waivers and blanket authority.

Filed Date: 10/19/2007.

Accession Number: 20071023–0029.

Comment Date: 5 p.m. Eastern Time on Friday, November 9, 2007.

Docket Numbers: ER08–76–000.

Applicants: South Glen Falls Energy, LLC.

Description: South Glen Falls Energy, LLC. submits a notice of cancellation of their market based rate tariff, FERC Electric Tariff, Third Revised Volume 1.

Filed Date: 10/22/2007.

Accession Number: 20071023–0035.

Comment Date: 5 p.m. Eastern Time on Tuesday, November 13, 2007.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES08–3–000.

Applicants: Kansas City Power & Light Company.

Description: Application of Kansas City Power & Light Company for Authorization under section 204(A) to Issue Short Term Debt.

Filed Date: 10/22/2007.

Accession Number: 20071022–5110.

Comment Date: 5 p.m. Eastern Time on Tuesday, November 13, 2007.

Take notice that the Commission received the following PURPA 210(m)(3) filings:

Docket Numbers: QM08–2–000.

Applicants: PECO Energy Company.

Description: Application of PECO Energy Company to terminate purchase obligation.

Filed Date: 10/19/2007.

Accession Number: 20071022–0151.

Comment Date: 5 p.m. Eastern Time on Friday, November 16, 2007.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR06–1–011.

Applicants: North American Electric Reliability Corporation.

Description: Compliance Filing of the North American Electric Reliability Corp in Response to September 20, 2007 Order.

Filed Date: 10/19/2007.

Accession Number: 20071019–5078.

Comment Date: 5 p.m. Eastern Time on Friday, November 9, 2007.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*. or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Acting Deputy Director.

[FR Doc. E7–21227 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2197–073; Project No. 2206–030]

Alcoa Power Generating, Inc., North Carolina; Progress Energy Carolinas, North Carolina; Notice of Public Meetings on Draft Environmental Impact Statement

October 23, 2007.

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of its staff will conduct two public meetings on the draft environmental impact statement (DEIS) for the Yadkin Hydroelectric Project and the Yadkin-Pee Dee River Hydroelectric Project. The times and locations of these meetings are as follows:

Yadkin Project Meeting

Date: November 14, 2007.

Time: 7 to 9:30 p.m. (EST).

Place: James Varick Auditorium.

Address: Livingstone College, 701 West Monroe Street, Salisbury, NC 28144.

Yadkin-Pee Dee Project Meeting

Date: November 15, 2007.

Time: 7 to 9:30 p.m. (EST).

Place: Cole Auditorium.

Address: Richmond Community College, 1042 West Hamlet Ave., Hamlet, NC 28345.

The purpose of these meetings is to solicit comments on the DEIS prepared for the relicensing applications of the Yadkin and Yadkin-Pee Dee River Projects. The DEIS was issued and publicly noticed on September 28, 2007, and is available for review on the Commission's Web site at *http://www.ferc.gov*, using the ''eLibrary'' link. Enter the docket number (either P–2197or P–2206) to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659.

The Yadkin Project is located on the Yadkin River in Davidson, Davie, Montgomery, Rowan, and Stanly Counties, North Carolina. The Yadkin-Pee Dee River Project is located on the Yadkin and Pee Dee Rivers in Anson, Montgomery, Richmond, and Stanly Counties, North Carolina. There are no federal lands affected by these projects.

These meetings are open to the public. All local, state, and federal agencies, Indian Tribes, and other interested parties are invited to participate. Transcripts of the meetings will be prepared.

The deadline for filing comments on the DEIS is December 8, 2007. Comments should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments should reference either Project No. 2197–073 (Yadkin Project) or Project No. 2206–030 (Yadkin-Pee Dee River Project). Comments may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and instructions on the Commission's Web site at *http://www.ferc.gov* under the eLibrary link.

For further information, contact Stephen Bowler at (202) 502–6861 or *stephen.bowler@ferc.gov* or Lee Emery at (202) 5028379 or *lee.emery@ferc.gov*.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21232 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12842–000]

FFP Project 19, LLC; Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

October 18, 2007.

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.:* 12842–000.

c. *Date filed:* July 25, 2007.

d. *Applicant:* FFP Project 19, LLC.

e. *Name of Project:* Brilliant Point Project.

f. *Location:* The project would be located on the Mississippi River in St James Parish, Louisiana. The project uses no dam or impoundment.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)—825(r).

h. *Applicant Contact:* Mr. Dan Irvin, FFP Project 19, LLC, 69 Bridge Street, Manchester, MA 01944, phone (978) 232–3536.

i. *FERC Contact:* Robert Bell, (202) 502–6062.

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: Kimberly D. Bose, 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. The Commission strongly encourages electronic filings. Please include the project number (P–12842–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor 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 consists of: (1) 2,600 proposed 20 kilowatt Free Flow generating units having a total installed capacity of 56 megawatts, (2) a proposed transmission line; and (3) appurtenant facilities. The FFP Project 19, LLC, project would have an average annual generation of 227.76 gigawatt-hours and be sold to a local utility.

l. *Locations of Applications:* A copy of the application is available for inspection and reproduction at the Commission in the Public Reference Room, located at 888 First Street NE., Room 2A, Washington DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the

document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Competing 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 and 4.36.

o. *Competing Development Application*—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 and 4.36.

p. *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.

q. *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.

r. *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.

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 ''e-filing'' link. The Commission strongly encourages electronic filing.

s. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''COMPETING APPLICATION'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''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. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

t. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21156 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12843–000]

FFP Project 23, LLC; Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

October 18, 2007.

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.:* 12843–000.

c. *Date filed:* July 25, 2007.

d. *Applicant:* FFP Project 23, LLC.

e. *Name of Project:* White Alder Project.

f. *Location:* The project would be located on the Mississippi River in St. Gabriel and Iberville Parishes, Louisiana. The project uses no dam or impoundment.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Dan Irvin, FFP Project 23, LLC, 69 Bridge Street, Manchester, MA 01944, phone (978) 232–3536.

i. *FERC Contact:* Robert Bell, (202) 502–6062.

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: Kimberly D. Bose, 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. The Commission strongly encourages electronic filings. Please include the project number (P–12843–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor 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 consists of: (1) 2,550

proposed 20 kilowatt Free Flow generating units having a total installed capacity of 51 megawatts, (2) a proposed transmission line; and (3) appurtenant facilities. The FFP Project 23, LLC, project would have an average annual generation of 223.38 gigawatt-hours and be sold to a local utility.

l. *Locations of Applications:* A copy of the application is available for inspection and reproduction at the Commission in the Public Reference Room, located at 888 First Street, NE., Room 2A, Washington DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Competing 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 and 4.36.

o. *Competing Development Application:* 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 and 4.36.

p. *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.

q. *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.

r. *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.

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 ''e-filing'' link. The Commission strongly encourages electronic filing.

s. *Filing and Service of Responsive Documents:* Any filings must bear in all capital letters the title ''COMMENTS'', ''COMPETING APPLICATION'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''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. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

t. *Agency Comments:* Federal, State, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21157 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12829–000; Project No. 12852–000]

Free Flow Power Corporation; FFP Project 8 LLC; Notice of Competing Applications Accepted for Filing and Soliciting Comments, Motions to Intervene, and Protests

October 19, 2007.

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection:

a. *Type of Applications:* Preliminary Permit (Competing).

b. *Applicants, Project Numbers, and Dates Filed:*

Free Flow Power Corporation, filed the application for Project No. 12829–000 on July 23, 2007.

FFP Project 8, LLC filed the application for Project No.12852–000 on July 25, 2007.

c. Name of the project is Greenville Bend Project. The project would be located on the Mississippi River in Orleans and Jefferson Counties, Louisiana. The project would use no dam or impoundment.

d. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a—825r.

e. *Applicants Contacts:* For the Free Flow Power Corporation: Mr. Dan Irvin, Free Flow Power Corporation, 69 Bridge Street, Manchester, MA 01944, phone (978) 232–3536. FFP Project 8, LLC:Mr. Dan Irvin, FFP Project 7, LLC, 69 Bridge Street, Manchester, MA 01944, phone (978) 232–3536.

f. *FERC Contact:* Robert Bell, (202) 502–6062.

g. *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: 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. The Commission strongly encourages electronic filings. Please include the project number (P–12829–000 or P–12852–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor 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.

h. *Description of Projects:* The project proposed by Free Flow Power Corporation would consist of: (1) 1,450 proposed 20 kilowatt Free Flow generating units having a total installed capacity of 19 megawatts, (2) a proposed transmission line; and (3) appurtenant facilities. The Free Flow Power Corporation, project would have an average annual generation of 127.02 gigawatt-hours and be sold to a local utility.

The project proposed by FFP Project 8, LLC would consist of: (1) 1,450 proposed 20 kilowatt Free Flow generating units having a total installed capacity of 29 megawatts, (2) a proposed transmission line; and (3) appurtenant facilities. The FFP Project 8, LLC, project would have an average annual generation of 127.02 gigawatt-hours and be sold to a local utility.

i. The filings are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCONLINESUPPORT@FERC.GOV*. For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item e above.

j. Competing 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 and 4.36.

k. Competing Development Application—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 and 4.36.

l. 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.

m. 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.

n. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', and ''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.

p. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21161 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP07–666–000; RP07–667–000]

Colorado Interstate Gas Company; Notice of Technical Conference

October 22, 2007.

Take notice that the Commission will convene a technical conference in the above-referenced proceeding on Thursday, November 15, 2007, at 10 a.m. (EDT), in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426.

The Commission's September 27, 2007 Order [1] directed that a technical

[1] Colorado Interstate Gas Co., 120 FERC ¶ 61,287 (2007).

conference be held to address the issues raised by Colorado Interstate Gas Company's (CIG) August 31, 2007, tariff filings to revise its fuel tracking mechanism and to update the calculation of its cash-out Index Price and cash-out System Index Price (collectively, cash-out prices).

Commission Staff and parties will have the opportunity to discuss all of the issues raised by CIG's proposals to modify its fuel and LUF mechanism and to adjust its cash-out price calculations. Specifically, CIG should be prepared to address all the concerns raised in the protests, and if necessary, to provide additional technical, engineering and operational support for its proposals. Any party proposing alternatives to CIG's proposals should also be prepared to similarly support its position.

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an e-mail to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or 202–502–8659 (TTY), or send a fax to 202–208–2106 with the required accommodations.

All interested persons are permitted to attend. For further information please contact Debbie-Anne Reese at (202) 502–8758 or e-mail *Debbie-Anne.Reese@ferc.gov*.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–21223 Filed 10–25–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Big Stone II Power Plant and Transmission Project Supplemental Draft Environmental Impact Statement (DOE/EIS–0377)

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of availability and public hearing.

SUMMARY: Western Area Power Administration (Western) announces the availability of the Supplemental Draft Big Stone II Power Plant and Transmission Project (Project) Environmental Impact Statement (Supplemental Draft EIS) for public review and comment. The U.S. Department of Agriculture Rural Utilities Service (RUS) and U.S. Department of Defense, U.S. Army Corps of Engineers (USACE), are participating as cooperating agencies in the EIS process. The Supplemental Draft EIS addresses the environmental impacts of a different back-up water supply plan that uses groundwater instead of surface water along with associated cooling alternatives for the proposed Big Stone II power plant's back-up water supply. The National Environmental Policy Act (NEPA) requires Western to make the Supplemental Draft EIS available to interested members of the public, groups, and Federal, State, local, and tribal agencies for review and comment to assure they have an opportunity to provide input to the Federal decision making process. Comments on the Supplemental Draft EIS may be provided in writing or at the hearing scheduled during the review period.

DATES: Western invites the public to comment on the Supplemental Draft EIS during the 45-day public review and comment period, which begins on October 26, 2007, and ends on Monday, December 10, 2007.

Western will hold one public hearing on November 13, 2007, at 7 p.m., at the Milbank Chamber of Commerce in Milbank, South Dakota.

ADDRESSES: The hearing will be held at the Milbank Chamber of Commerce, 1001 E. 4th Ave., Milbank, South Dakota.

Written comments on the Supplemental Draft EIS should be mailed, faxed, or e-mailed to: Ms. Nancy Werdel, NEPA Document Manager, Big Stone II EIS, A7400, Western Area Power Administration, P.O. Box 281213, Lakewood, CO 80228–8213, fax (720) 962–7263 or 7269, e-mail *BigStoneEIS@wapa.gov*.

FOR FURTHER INFORMATION CONTACT: For further information or to request a copy or summary of the Supplemental Draft EIS, please write Ms. Nancy Werdel, NEPA Document Manager, Big Stone II EIS, A7400, Western Area Power Administration, P.O. Box 281213, Lakewood, CO 80228–8213, fax (720) 962–7263 or 7269, e-mail *BigStoneEIS@wapa.gov*, or telephone her at (800) 336–7288.

For general information on DOE's NEPA review process, please contact: Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance, GC–20, U.S. Department of Energy, Washington, DC 20585, (202) 586–4600 or (800) 472–2756.

SUPPLEMENTARY INFORMATION: In May 2006, Western Area Power Administration (Western) issued the Big Stone II Power Plant and Transmission Project Draft Environmental Impact Statement (Draft EIS). The Draft EIS described the details of the Proposed Action to construct a nominal 600-megawatt (MW), coal-fired, baseload electric generating facility and associated transmission line and substation upgrades, known as the Big Stone II Project (proposed Project). The primary source of water for the existing plant and the proposed Big Stone II plant would be withdrawals from Big Stone Lake. The proposed Project described in the Draft EIS included construction of a 450-acre surface water pond as the source of back-up water. The 450-acre surface water pond would have been filled with water from Big Stone Lake during normal operating conditions and used in the event of a drought or operational constraints, when sufficient quantities of water could not be pumped from Big Stone Lake. The Rural Utilities Service (RUS) and the U.S. Army Corps of Engineers (USACE) are participating as cooperating agencies in the EIS process.

The purpose of the Supplemental Draft EIS is to present and analyze the environmental impacts of using groundwater instead of surface water for the proposed Big Stone II power plant's back-up water supply along with different cooling alternatives. Changes to the proposed Project are based on comments received on the Draft EIS concerning wetland impacts from construction of the 450-acre water storage pond and additional construction costs associated with the pond.

The Council on Environmental Quality NEPA regulations (40 CFR 1502.9) and DOE NEPA regulations (10 CFR 1021.314) require that a supplement to a draft environmental impact statement be prepared if there are substantial changes to the Proposed Action or significant new circumstances or information relevant to environmental concerns, and contribute to the impacts of the Proposed Action. Western determined that the use of groundwater as the back-up water supply would significantly change the environmental impacts of the proposed Project as presented in the Draft EIS and required the preparation of a Supplemental Draft EIS.

The Supplemental Draft EIS considers two cooling technology alternatives with groundwater as the back-up water supply. Groundwater would be produced from the Veblen Aquifer. Both alternatives would use surface water from Big Stone Lake as the primary water source. Alternative 2 (wet cooling with groundwater back-up water supply), the Revised Proposed Action, retains the original wet cooling system technology identified in the Draft EIS but uses groundwater supply as its back-up water supply. Alternative 3 (wet/dry

cooling with groundwater back-up water supply) would use a combined wet/dry cooling system. The dry portion would use an air-cooled condenser as a heat transfer mechanism and the wet portion of the system would be used in parallel to the dry system, as needed, to achieve full unit output on warmer days. Both alternatives would require installation of groundwater production wells and a pipeline system to convey groundwater to the proposed plant site. Other changes described in the Supplemental Draft EIS include plant water usage, water treatment, and wastewater management. There are no other significant changes to the Proposed Action as described in Section 2.2 of the Draft EIS.

The Supplemental Draft EIS evaluates the environmental impacts of the proposed Project on air quality, water resources (groundwater, floodplains, surface water), geology, minerals, paleontological resources, soils, biological resources (vegetation, wildlife, fisheries, special status species, wetland/riparian areas), cultural and historical resources, land use (land use planning, public facilities, recreation, agricultural practices and prime and unique farmland), infrastructure, public health, waste management, visual resources, noise, social and economic values, environmental justice, and cumulative impacts.

Western maintains a mailing list of those interested in the Big Stone II Project EIS. Copies of the complete Supplemental Draft EIS or the Executive Summary have been distributed to all persons and groups on the mailing list that requested a copy. A distribution has been made to various libraries in the proposed Project area.

Oral comments on the Supplemental Draft EIS will be accepted only during the public hearing scheduled for the date and location provided above. Those wishing to make oral comments may do so at the scheduled public hearing. Speakers will be asked to register at the door prior to the beginning of the hearing. Speakers are encouraged to provide a written version of their oral comments for the record. Each speaker will be allowed 5 minutes to present comments unless more time is requested and available. Comments will be recorded by a court reporter at the hearing and will become part of the public hearing record. Western will conduct an open house information session 2 hours prior to the public hearing to field questions and provide information to the public.

Copies of the Supplemental Draft EIS are available for public review at the offices and public libraries listed below:

Public Libraries

Ortonville Public Library, 412 Second Street Northwest, Ortonville, Minnesota.

Morris Public Library, 102 East 6th Street, Morris, Minnesota.

Granite Falls Public Library, 155 7th Avenue, Granite Falls, Minnesota.

Appleton Public Library, 322 W. Schlieman Avenue, Appleton, Minnesota.

Canby Public Library, 110 Oscar Avenue North, Canby, Minnesota.

Willmar Public Library, 410 5th Street Southwest, Willmar, Minnesota.

Kerkhoven Public Library, 208 10th Street North, Kerkhoven, Minnesota.

Benson Public Library, 200 13th Street South, Benson, Minnesota.

Grant County Public Library, 207 Park Avenue East, Milbank, South Dakota.

Watertown Regional Library, 611 Bruhn Avenue NE., Watertown, South Dakota.

The Draft EIS is also available at DOE Reading Rooms at the following addresses:

U.S. Department of Energy, Forrestal Building, Reading Room 1E–190, 1000 Independence Avenue, SW., Washington, DC 20585; Western Area Power Administration, Corporate Services Office, 12155 West Alameda Parkway, Lakewood, Colorado 80228; and Western Area Power Administration, Upper Great Plains Customer Service Region, South Dakota Maintenance Office, 200 4th Street, SW., Huron, South Dakota 57350.

Western will consider all written comments postmarked or received during the public comment period in preparing the Final EIS. Decisions by each of the involved Federal agencies will be made after considering comments on the Draft, Supplemental Draft, and Final EIS. The decisions to be made by Western, RUS, and USACE regarding the proposed Big Stone II Power Plant and Transmission Project will be issued following the Final EIS in the form of separate records of decision for each agency.

Dated: October 19, 2007.

Timothy J. Meeks,

Administrator.

[FR Doc. E7–21088 Filed 10–25–07; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8487–8]

Science Advisory Board Staff Office; Request for Additional Expertise for the Science Advisory Board Asbestos Expert Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office is seeking public nominations of additional experts in the formation of the Asbestos Expert Panel in the areas of biostatistics, statistical modeling, epidemiology, meta-analysis, Bayesian analysis and toxicology of inhaled particles. Previous nominations of individuals for this asbestos panel need not be re-submitted, as they will still be considered.

DATES: New nominations should be submitted by November 16, 2007.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain further information regarding this announcement may contact Ms. Vivian Turner, Designated Federal Officer, by telephone: (202) 343–9697 or e-mail at: *turner.vivian@epa.gov.* The SAB Mailing address is: U.S. EPA Science Advisory Board (1400F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. General information about the SAB as well as any updates concerning this request for nominations may be found on the SAB Web site at: *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION: EPA's Office of Solid Waste and Emergency Response (OSWER) requested the Science Advisory Board (SAB) provide technical advice on the proposed methodology to estimate cancer potency from inhalation exposure to asbestos. In 71 FR 48926–48927, the SAB announced the formation of an Asbestos Expert Panel and solicited nominations for members to that Panel. In response to that **Federal Register** Notice, the SAB Staff Office received nominations in the areas of clinical and pulmonary medicine, epidemiology, occupational and public health, pathology, inhalation toxicology; biology, mineralogy; environmental fate and transport, environmental sampling and detection methods, biostatistics, statistical modeling and risk assessment.

The Science Advisory Board Staff Office is now seeking additional nominations for nationally and internationally recognized non-EPA scientists who have expert knowledge in

biostatistics, statistical modeling, epidemiology, meta-analysis, Bayesian analysis and toxicology of inhaled particles.

The SAB is a chartered Federal Advisory Committee, established by 42 U.S.C. 4365, to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical bases for EPA policies and actions. The SAB expert panel will provide technical advice to EPA through the chartered SAB. The SAB Asbestos Panel will comply with the provisions of the Federal Advisory Committee Act (FACA) and all appropriate SAB procedural policies.

Request for Nominations: The SAB Staff Office is requesting nominations for nationally and internationally recognized non-EPA scientists with demonstrated expertise in biostatistics, statistical modeling, epidemiology, meta-analysis, Bayesian analysis and toxicology of inhaled particles. The previously submitted nominations of individuals for this Asbestos Expert Panel need not be re-submitted, as they will still be considered.

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate individuals qualified in the areas of expertise described above to serve on the SAB Asbestos Expert Panel. Nominations may be submitted in electronic format through the *Form for Nominating Individuals to Panels of the EPA Science Advisory Board* which can be accessed through a link on the blue navigational bar on the SAB Web site at: *http://www.epa.gov/sab.* Please follow the instructions for submitting nominations carefully, and include all of the information requested on that form. The nominating form requests contact information of the person making the nomination; contact information for the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's curriculum vita; and a biographical sketch of the nominee indicating current position, educational background, research activities, and recent service on other national advisory committees or national professional organizations. Anyone unable to submit nominations using the electronic form, or who may have questions concerning the nomination process or any other aspect of this notice may contact Ms. Vivian Turner, DFO, at the contact information. Nominations should be submitted in time to arrive no later than November 16, 2007.

The process for forming an SAB panel is described in the *Overview of the Panel Formation Process at the Environmental Protection Agency, Science Advisory Board* (EPA–SAB–EC–COM–02–010), on the SAB Web site at: *http://www.epa.gov/sab/pdf/ec02010.pdf.* The SAB Staff Office will acknowledge receipt of nominations and inform nominees of the panel for which they have been nominated. From the nominees identified by respondents to this **Federal Register** notice (termed the ''Widecast''), the SAB Staff Office will develop a smaller subset (known as the ''Short List'') for more detailed consideration. The Short List will be posted on the SAB Web site at: *http://www.epa.gov/sab* and will include the nominee's name and biographical sketch. Public comments on the Short List will be accepted for 21 calendar days. During this comment period, the public will be requested to provide information, analysis or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates for the panel.

For the SAB, a balanced panel is characterized by inclusion of nominees who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the charge. Public responses to the Short List will be considered in the selection of the panel members, along with information provided by nominees and information independently gathered by SAB Staff (e.g., financial disclosure information and computer searches to evaluate a nominee's prior involvement with the topic under review). Specific criteria to be used in evaluating Short List nominees include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) absence of financial conflicts of interest; (c) scientific credibility and impartiality; (d) availability and willingness to serve; and (e) ability to work constructively and effectively on committees.

Dated: October 19, 2007.

Anthony F. Maciorowski,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. E7–21092 Filed 10–25–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL6692–4]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at 202–564–7167.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 6, 2007 (72 FR 17156).

Draft EISs

EIS No. 20070285, ERP No. D–COE–K35044–CA, Berth 136–147 [TraPac] Container Terminal Project, Upgrade Existing Wharf Facilities, Install a Buffer Area between the Terminal and Community, US Army COE Section 10 and 404 Permit, West Basin Portion of the Port of Los Angeles, CA.

Summary: EPA expressed environmental concerns because the preferred alternative may not represent the least environmentally damaging practicable alternative, as required under the Clean Water Act Section 404(b)(1) Guidelines. EPA also expressed environmental concerns about impacts to air quality and minority and low-income communities, and requested that the Final EIS discuss mitigation in more detail. Rating EC2.

EIS No. 20070296, ERP No. D–AFS–K65332–CA, Eldorado National Forest Public Wheeled Motorized Travel Management Project, Proposes to Regulate Unmanaged Public Wheeled Motor Vehicle, Implementation, Alpine, Amador, El Dorado and Placer Counties, CA.

Summary: EPA expressed environmental concerns about impacts to water quality, meadows, riparian areas, critical habitat, and watersheds, and requested additional information on the above issues, monitoring and enforcement commitments. Rating EC2.

EIS No. 20070297, ERP No. D–AFS–J65486–UT, Big Creek Vegetation Treatment Project, To Treat 4,800 Acres of Aspen Conifer and Sagebrush Communities, Ogden Ranger District, Wasatch-Cache National Forest, Rich County, UT.

Summary: While EPA does not object to the proposed action, it requested

clarification of impacts to migratory birds, regeneration of big sagebrush, and mitigation of impacts from illegal ORV use. Rating LO.

EIS No. 20070315, ERP No. D–NOA–L91029–AK, Alaska Eskimo Whaling Commission for a Subsistence Hunt on Bowhead Whale for the Years 2008 through 2012 for Issuing Annual Quotas, Proposes to Authorize Subsistence Harvests of the Western Arctic Stock of Bowhead Whales, Bering, Chukchi and Beaufort Seas, AK.

Summary: While EPA does not object to the proposed action, it requested clarification on the exchange of non-food portions of the whales between native villages as a commodity. Rating LO

EIS No. 20070365, ERP No. D–USA–A15000–00, PROGRAMMATIC—Army Growth and Force Structure Realignment, Implementation, Nationwide.

Summary: EPA does not object to the proposed action. Rating LO.

EIS No. 20070393, ERP No. DS–AFS–J65424–MT, Fishtrap Project, Updated Information on Past Maintenance/Restorative Treatments within Old Growth Stands, 200 Timber Harvest, Prescribed Burning, Road Construction and Other Restoration Activities, Lolo National Forest, Plains/Thompson Falls Ranger District, Sanders County, MT.

Summary: EPA does not object to the proposed action. Rating LO.

Final EISs

EIS No. 20070260, ERP No. F–COE–K36142–CA, PROGRAMMATIC—San Luis Obispo Creek Watershed, Waterway Management Plan, Stream Maintenance and Management Plan, City of San Luis Obispo and County of San Luis Obispo, Community of Avila Beach, San Luis Obispo County, CA.

Summary: EPA's previous issues have been resolved; therefore, EPA does not object to the proposed action.

EIS No. 20070292, ERP No. F–COE–K36055–CA, San Luis Rey Flood Control Project, Operation and Maintenance of the Vegetation and Sediment Management, from College Blvd to the Pacific Ocean, San Diego County, CA.

Summary: EPA continues to have environmental concerns because the preferred alternative may not represent the least environmentally damaging practicable alternative, as required under the Clean Water Act section 404(b)(1) Guidelines.

EIS No. 20070318, ERP No. F–FHW–K40257–CA, Los Banos Bypass Project, Construct from CA–152 in Merced County beginning near Volta Road west to Los Banos, bypassing Los Banos, ending near the Santa Fe Grade Road, U.S. Army COE Section 404 Permit, Merced County, CA.

Summary: EPA continues to have environmental concerns about the proposed project related to induced growth. Also, EPA recommends that the project sponsor develop a strategy to facilitate protection of valuable habitat areas.

EIS No. 20070379, ERP No. F–AFS–L65525–AK, Baht Timber Sale Project, Proposes to Harvest Timber and Temporary Road Construction on Zarembo Island, Wrangell Ranger District, Tongass National Forest, AK.

Summary: EPA continues to have concerns about potential impacts to water quality and impacts to old growth habitat, and recommends water quality monitoring, preservation of riparian buffers and reduced new road construction.

EIS No. 20070402, ERP No. F–FRC–K03030–00, Phoenix Expansion Project, Construction and Operation of Existing Natural Gas Transmission Pipeline, Right-of-Way Grant and Temporary Use Permit, San Juan and McKinley Counties, NM and Pinal and Maricopa Counties, AZ.

Summary: No formal comment letter was sent to the preparing agency.

EIS No. 20070058, ERP No. FA–FHW–E40325–NC, Western Section of the Winston-Salem Northern Beltway, Updated Information, U.S. 158 north to U.S. 52, TIP Project No. R–2247, Forsyth County, NC. (THIS EIS #20070058 AND EIS #20070057 ARE COMBINED IN A SINGLE DOCUMENT.)

Summary: EPA continues to have environmental concerns about the large bypass regarding 7–8 linear miles of stream impacts, sedimentation and erosion control, terrestrial forest habitat losses and impacts to migratory birds. EPA requests that the Record of Decision disclose plans to mitigate these adverse impacts.

EIS No. 20070384, ERP No. FS–FHW–E40714–GA, U.S. 411 Connector, From U.S. 411/GA–20 Interchange with U.S. 41 to U.S. 411 Interchange with I–75, Updated Information, Funding and U.S. Army COE Section 404 Permit, Bartow County, GA.

Summary: EPA continues to have environmental concerns about the preferred alternative regarding impacts to jurisdictional wetlands, regulatory floodplains, and the loss of upland forest habitat. However, EPA supports the mitigation measures and monitoring programs as described in the Final Supplemental EIS.

Dated: October 23, 2007.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E7–21089 Filed 10–25–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6692–3]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 10/15/2007 through 10/19/2007.

Pursuant to 40 CFR 1506.9.

EIS No. 20070435, Draft EIS, BLM, UT, Richfield Field Office Resource Management Plan, Implementation, Future Management of the Public Lands and Resource, Glen Canyon National Recreation Area, Capitol Reef and Canyonlands National Parks, Sanpete, Sevier, Piute, Wayne and Garfield Counties, UT. *Comment Period Ends:* 01/24/2008. *Contact:* Wayne Wetzel, 435–896–1500.

EIS No. 20070436, Draft EIS, FHW, ME, Wiscasset Route 1 Corridor Study Project, To Relieve Traffic Congestion and Improve Safety, U.S. Army COE section 404 Permit, Wiscasset and Edgecomb Counties, ME. *Comment Period Ends:* 12/21/2007. *Contact:* Mark Asselmann, 207622–8350.

EIS No. 20070437, Draft EIS, NPS, HI, PROGRAMMATIC EIS—Ala Kahakai National Historic Trail Comprehensive Management Plan, To Provide Long-Term Direction for Natural and Cultural Resource, Island of Hawii, HI. *Comment Period Ends:* 12/26/2007. *Contact:* Aric Arakaki 808–326–6012.

EIS No. 20070438, Final Supplement, NOA, NC, Atlantic Sea Scallop Fishery Management Plan (FMP), Amendment 11, Implementation to Control Capacity and Mortality in the General Category Scallop Fishery, Gulf of Maine, Georges Bank, NC. *Wait Period Ends:* 11/26/2007. *Contact:* Patricia A. Kurkal, 978–281–9250.

EIS No. 20070439, Draft EIS, BOP, AL, Aliceville, Alabama Area, Proposed

Federal Correctional Complex, To Address the Growing Federal Inmate Population, Pickens County, AL. *Comment Period Ends:* 12/10/2007. *Contact:* Pamela J. Candler, 202–514–6470.

EIS No. 20070440, Draft EIS, FHW, UT, Mountain View Corridor (MVC) Project, Proposed Transportation Improvement 2030 Travel Demand in Western Salt Lake County south of I–80 and west of Bangerter Highway and in northwestern Utah County of I–15, south of the Salt Lake County Line, and north of Utah Lake, Salt Lake and Utah County, UT. *Comment Period Ends:* 12/24/2007. *Contact:* Edward Woolford, P.E. 801–963–0182.

EIS No. 20070441, Draft Supplement, IBR, CA, PROGRAMMATIC—Environmental Water Account (EWA) Project, Updated Information to Provide an Evaluation of 2004 Final EIS/EIR Environmental Water Account (EWA) and Effects Associated with Extending the Current EWA's through 2011, CALFED Bay-Delta Programs, Endangered Species Act section 7 and U.S. Army COE Section 10 Permit, CA. *Comment Period Ends:* 12/10/2007. *Contact:* Ms. Sammie Cervantes, 916–978–5104.

EIS No. 20070442, Final EIS, FHW, CA, Interstate 5/Cosumnes River Boulevard Interchange Project, Extension of Cosumnes River Boulevard from Franklin Boulevard to Freeport Boulevard with an Interchange at Interstate 5, South of the Pocket/Meadowview Road Interchange and North of the Laguna Boulevard Interchange, City of Sacramento, Sacramento County, CA. *Wait Period Ends:* 11/26/2007. *Contact:* Cesar E. Perez, 916–498–5065.

EIS No. 20070443, Draft Supplement, FTA, CA, Third Street Light Rail Phase 2, Updated Information on the Central Subway Project Area, Funding, San Francisco Municipal Transportation Agency, in the City and County San Francisco, CA. *Comment Period Ends:* 12/10/2007. *Contact:* Ray Sukys, 415–744–3133.

EIS No. 20070444, Final EIS, USA, GA, Fort Benning U.S. Army Infantry Center, Base Realignment and Closure (BRAC) 2005 and Transformation Actions, Implementation, Chattahoochee and Muscogee Counties, GA. *Wait Period Ends:* 11/26/2007. *Contact:* John Brent, 706–545–2180.

EIS No. 20070445, Draft EIS, USN, 00, Shock Trail of the MESA VERDE (LPD 19), San Antonio (LPD 17) Class Ship designated as the Shock Ship for Proposed Shock Trail, Possible Offshore Locations are Naval Station Norfolk, VA; Naval Station Mayport, FL; and Naval Air Station Pensacola, FL. *Comment Period Ends:* 12/10/2007. *Contact:* Donald Shaver, 703–412–7521.

EIS No. 20070446, Final EIS, FHW, IN, I–69 Evansville to Indianapolis Project, I–69 Tier 2 Section 1: Evansville to Oakland City, from 1–64 to IN–64, Preferred Alternative is 4, Gibson and Warrick Counties, IN. *Wait Period Ends:* 11/26/2007. *Contact:* Anthony DeSimone, 317–226–5307.

EIS No. 20070447, Draft EIS, FHW, CA, Marin-Sonoma Narrows (MSN) HOV Widening Project, Propose to Relieve Recurrent Congestion along U.S. 101 south of the Route 37 Interchange in the City of Novato (Marin County) and ends north of the Corona Road Overcrossing in the City of Petaluma (Sonoma County), Marin and Sonoma Counties, CA. *Comment Period Ends:* 12/14/2007. *Contact:* Cesar E. Perez, 916–498–5065.

EIS No. 20070448, Final EIS, USA, 00, PROGRAMMATIC—Army Growth and Force Structure Realignment, Implementation, Nationwide. *Wait Period Ends:* 11/26/2007. *Contact:* Mike Ackerman, 410–436–2522.

EIS No. 20070449, Final EIS, BLM, ID, Smoky Canyon Mine Panels F & G, Proposed Mine Expansion, Caribou County, ID. *Wait Period Ends:* 11/26/2007. *Contact:* Bill Stout 208–478–6367.

EIS No. 20070450, Draft Supplement, WPA, 00, Big Stone II Power Plant and Transmission Project, Addresses the Impacts of Changes to the Proposed Action relative to Cooling Alternatives and the Use of Groundwater as Backup Water Source, U.S. Army COE Section 10 and 404 Permits, Grant County, SD and Big Stone County, MN. *Comment Period Ends:* 12/10/2007. *Contact:* Nancy Werdel, 720–962–7251.

EIS No. 20070451, Draft EIS, AFS, UT, Indian Springs Road Realignment, Reducing Adverse Impacts to Watershed and Fisheries, U.S. Army COE Section 404 Permit, Uinta National Forest, Heber Ranger District, Wasatch County, UT. *Comment Period Ends:* 12/10/2007. *Contact:* Jim Percy, 435–654–0470.

Dated: October 23, 2007.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E7–21102 Filed 10–25–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[Docket# EPA–RO4–SFUND–2007–1052; FRL–8487–9]

B&B Manufacturing Superfund Site; Mobile, Mobile County, AL; Notice of Settlements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of settlements.

SUMMARY: Under Section 122(h) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the United States Environmental Protection Agency has entered into three separate settlements for reimbursement of past response costs concerning the B&B Manufacturing Superfund Site located in Mobile, Mobile County, Alabama.

DATES: The Agency will consider public comments on the settlements until November 26, 2007. The Agency will consider all comments received and may modify or withdraw its consent to the settlements if comments received disclose facts or considerations which indicate that the settlements are inappropriate, improper, or inadequate.

ADDRESSES: Copies of the settlements are available from Ms. Paula V. Batchelor. Submit your comments, identified by Docket ID No. EPA–RO4–SFUND–2007–1052 or Site name B&B Manufacturing Superfund Site by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: Batchelor.Paula@epa.gov.*
- *Fax:* 404/562–8842/Attn: Paula V. Batchelor.

Mail: Ms. Paula V. Batchelor, U.S. EPA Region 4, SD–SEIMB, 61 Forsyth Street, SW., Atlanta, Georgia 30303. ''In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.

Instructions: Direct your comments to Docket ID No. EPA–RO4–SFUND–2007–1052. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you

consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the U.S. EPA Region 4 office located at 61 Forsyth Street, SW., Atlanta, Georgia 30303. Regional office is open from 7 a.m. until 6:30 p.m. Monday through Friday, excluding legal holidays.

Written comments may be submitted to Ms. Batchelor within 30 calendar days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: Paula V. Batchelor at 404/562–8887.

Dated: October 11, 2007.

Rosalind H. Brown,

Chief, Superfund Enforcement & Information Management Branch, Superfund Division.

[FR Doc. E7–21094 Filed 10–25–07; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board Through an Expedited Review Procedure

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP) is requesting written comments on a proposed amendment to item 5 of the categories of research that may be reviewed by the institutional review board (IRB) through an expedited review procedure, last published in the **Federal Register** on November 9, 1998 (63 FR 60364). On that date, the Office for Protection from Research Risks (OPRR), now OHRP, and the Food and Drug Administration (FDA) simultaneously published identical lists of categories of research activities involving human subjects which may be reviewed by the IRB through an expedited review procedure. It has come to OHRP's attention that there has been confusion in the research community about expedited review category 5. OHRP is proposing to amend expedited review category 5 to clarify that the category includes research involving materials that were previously collected for either nonresearch or research purposes, provided that any materials collected for research were not collected for the currently proposed research. Expedited review category 5 also includes research involving materials that will be collected solely for nonresearch purposes.

In addition, OHRP is requesting comments on the entire expedited review list that was last published in the **Federal Register** on November 9, 1998 (63 FR 60364) to determine if other changes are needed.

As part of its charge to provide expert advice and recommendations to the Secretary of Health and Human Services (the Secretary) and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects, the Secretary's Advisory Committee on Human Research Protections (SACHRP), through its Subcommittee on Subpart A, considered whether the current expedited review categories should be modified. On March 14, 2007, SACHRP submitted recommendations regarding expedited review to the Secretary, and on June 18, 2007, the Secretary sent a letter to the SACHRP chairperson, stating that HHS would give serious consideration to these recommendations. In regard to the current expedited review categories, SACHRP recommended that expedited review category 7 should be revised as described in Section V below. Therefore, in addition to requesting comments on the entire expedited review list that was published in the **Federal Register** on November 9, 1998 (63 FR 60364), OHRP is also specifically requesting comments on SACHRP's recommended revision of expedited review category 7.

As required under 21 CFR 56.110(a), FDA also will publish in the **Federal Register** a list of categories of research that may be reviewed by the IRB through an expedited review procedure. FDA intends to issue the list concurrently with OHRP's issuance of its final notice, and in compliance with 21 CFR 10.115 (good guidance practice regulations). This approach maintains FDA's practice of moving in tandem on this issue with OHRP.

DATES: Submit written or electronic comments by December 26, 2007.

ADDRESSES: Submit written comments to EXPEDITED REVIEW, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to *expeditedreviewohrp@hhs.gov*, or via facsimile at 301–402–2071. Comments received within the comment period, including any personal information provided, will be made available to the public upon request.

FOR FURTHER INFORMATION CONTACT: Mr. Glen Drew, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 1–866–447–4777 or by e-mail to: *glen.drew@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Expedited Review Procedures

The Department of Health and Human Services (HHS) human subjects protection regulations at 45 CFR 46.110 permit expedited review procedures for certain kinds of human subjects research that have been found by an IRB to involve no more than minimal risk to research subjects, or for minor changes in previously IRB-approved research during the period (of one year or less) for which approval is authorized. An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB, in

accordance with the requirements at 45 CFR 46.110.

The HHS regulations at 45 CFR 46.110 also give the Secretary the authority to amend and republish the list of research categories that may be reviewed by the IRB through an expedited review procedure, after consultation with other departments and agencies. This same section of the HHS regulations also requires that an amended expedited review list be published by the Secretary in the **Federal Register**.

As required by HHS regulations at 45 CFR 46.110, this proposed amendment of expedited review category 5 was developed after consulting with the other Federal departments and agencies that have promulgated the Federal Policy for the Protection of Human Subjects.

II. Background on the Expedited Review List

The first expedited review list was published by the Secretary in 1981 (46 FR 8392). On November 10, 1997, OPRR, now OHRP, and FDA published identical proposed revisions to the 1981 expedited review list (published for OPRR at 62 FR 60607). The category of research in question, expedited review category 5, was addressed in the proposed categories 4 and 5 in the November 10, 1997 **Federal Register** Notices requesting public comment. In those Notices, proposed categories 4 and 5 were presented as follows:

> (4) Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens) where these materials, in their entirety, have been collected prior to the research, for a purpose other than the proposed research.
>
> (5) Research involving solely (a) prospectively collected identifiable residual or discarded specimens, or (b) prospectively collected identifiable data, documents, or records, where (a) or (b) has been generated for nonresearch purposes.

In addition, a chart included in OPRR's and FDA's November 10, 1997 **Federal Register** Notices, comparing the proposed expedited review list with the 1981 list, indicated that the proposed category 4 (see above) was intended to replace expedited review category 8 on the 1981 list. Category 8 on the 1981 list stated, ''the study of existing data, documents, records, pathological specimens, or diagnostic specimens.''

The comments received on OPRR's and FDA's November 10, 1997 **Federal Register** Notices overwhelmingly supported the proposed revision to the expedited review list. With minor modifications to the 1997 proposed expedited review list, on November 9, 1998, OPRR and FDA simultaneously published identical revised lists of categories of research activities that may be reviewed by the IRB through the expedited review procedure (published for OPRR at 63 FR 60364, and for FDA at 63 FR 60353). In regard to expedited review category 5, the OPRR and FDA November 9, 1998 **Federal Register** Notices described this category of research as:

> (5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

The preamble of the OPRR November 9, 1998 **Federal Register** Notice explained that:

> Categories four (4) and five (5) on the proposed list have been combined into one new category five (5) on the 1998 list. This new section is added in response to comments that raised questions about the relationship of proposed categories four (4) and five (5) to exempt research and about separating out existing and prospectively collected materials. The term ''nonresearch purposes'' was maintained in new category five (5) to describe the origins of the research material * * *

Similarly, the FDA November 9, 1998 **Federal Register** Notice explained that:

> Categories four and five on the proposed list have been combined into one new category, category five, addressing research involving materials collected or which will be collected solely for nonresearch purposes. This new category five was formed in response to comments that raised questions about why the two categories separated out existing and prospectively collected materials. The term ''nonresearch purposes'' was maintained in new category five to describe the origins of the research materials.

III. Clarification on the Scope of Expedited Review Category Five (5) Needed

The description of expedited review category 5 and the preamble language as published in the November 9, 1998 OPRR and FDA **Federal Register** Notices has caused confusion in the research community about whether this expedited review category includes research involving materials that were originally collected for either nonresearch or research purposes, or is limited to research involving materials that were originally collected solely for nonresearch purposes.

As evidence of this confusion, in their 1999 report, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance,* the National Bioethics Advisory Commission (NBAC) stated:

> NBAC finds that there is no need to distinguish between collections originally created for clinical purposes and those created for research purposes. In both cases, research on the collected materials should be eligible for expedited review if the research presents no more than a minimal risk to the study subjects.

As a result of this finding, NBAC recommended that ''OPRR should revise its guidance to make clear that all minimal-risk research involving human biological materials—regardless of how they were collected—should be eligible for expedited IRB review.'' In response to NBAC's 1999 report, HHS convened a multi-agency Working Group to analyze the appropriateness, feasibility, and practical implications of implementing NBAC's recommendations and to develop a set of proposed HHS activities to enhance the protection of human subjects in research involving human biological materials. In regard to the NBAC recommendation above, the HHS Working Group stated:

> The Working Group concurs with Recommendation 2 and agrees with NBAC that, for purposes of determining eligibility for expedited IRB review, it is not necessary to draw a distinction between samples originally collected for clinical purposes and those obtained for research purposes. The Working Group also agrees with NBAC's observation that current guidance regarding the types of research that IRBs may review through expedited procedures (63 FR 60364 [HHS] and 60353 [FDA], November 9, 1998) appears to exclude research utilizing existing specimens previously collected for research purposes. It is the understanding of the Working Group that this apparent exclusion is not intentional but rather resulted from a copy editing oversight * * *

IV. OHRP Assessment

After reviewing OPRR's and FDA's 1997 and 1998 **Federal Register** notices concerning revisions to the 1981 expedited review list, NBAC's recommendation, and the HHS Working Group's response, OHRP has concluded that expedited review category 5 was intended to, and should, include research involving existing information or specimens that were previously collected for *nonresearch* purposes, as well as research involving existing information or specimens that were previously collected for *research* purposes—provided they were not collected for the currently proposed research.

OHRP notes that neither OPRR's nor FDA's November 10, 1997 **Federal Register** Notice indicated that the proposed expedited review category 4

was intended to narrow category 8 on the 1981 list to exclude existing specimens that were collected for research purposes, provided the materials were collected for a research purpose other than the proposed research. Because proposed category 4 would have applied to research involving existing identifiable information or specimens that had been previously collected for *either research or nonresearch purposes,* provided they were not collected for the currently proposed research, OHRP has concluded that the term ''nonresearch purposes'' was retained in the final version of category 5 to describe the origins of the prospectively collected material only, not the origins of the previously collected material. However, this intent was not made clear in either OPRR's or FDA's November 9, 1998 **Federal Register** Notice.

V. OHRP Request for Comments

For the reasons described in Section IV, OHRP is proposing to revise expedited review category 5 as set forth below.

Remove (5) in its entirety, and add, in its place:

(5) Research involving materials (data, documents, records, or specimens) that

(a) have previously been collected for nonresearch purposes;

(b) have previously been collected for research purposes, provided the materials were not collected for the currently proposed research; or

(c) will be collected solely for nonresearch purposes.

Note: Some research under section (a) or (b) of this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

OHRP is also requesting comments on the entire expedited review list that was last published in the **Federal Register** on November 9, 1998 (63 FR 60364) to determine if other changes are needed. The following is the current expedited review list, as published in the **Federal Register** on November 9, 1998:

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children,[2] considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

In addition to requesting comments on all of the expedited review categories listed above, OHRP specifically requests comments on a recommendation by SACHRP to revise expedited review category 7 as follows:

Research (a) on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, affective states, interpersonal relationships, identity, language, communication, cultural beliefs or practices, and social behavior); or (b) employing methods commonly used in social, behavioral, epidemiologic, health services and educational research (including, but not limited to, survey, interview, oral history, participant observation, ethnographic, focus group, program evaluation, human factors evaluation, or quality assurance methods). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Dated: October 22, 2007.

Ivor A. Pritchard,

Acting Director, Office for Human Research Protections.

[FR Doc. E7–21126 Filed 10–25–07; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH–091]

Notice of Public Meeting

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting on updating the NIOSH publication ''Occupational Exposure Sampling Strategies Manual''.

The document can be found at *http://www.cdc.gov/niosh/docs/77–173/* .

Instructions are provided for submitting comments.

Public Meeting Dates and Times: November 8, 2007, 8:30 a.m. to 4:30 p.m. EST and November 9, 2007, 8:30 a.m. to 12 p.m. EST.

Place: Washington Court Hotel, 525 New Jersey Avenue, NW., Washington, DC 20001.

Purpose of Meeting: To obtain input from stakeholders on their needs for information and guidance to be included in a revision of the ''Occupational Exposure Sampling Strategies Manual'' (OESSM), which is sometimes referred to as ''Leidel, Busch and Lynch'' or ''The NIOSH Yellow Book'' [*http://www.cdc.gov/niosh/77–173.html*].

Status: The forum will include scientists and representatives from various government agencies, industry, labor, and other stakeholders, and is open to the public, limited only by the space available. Persons wanting to attend and contribute comments at the meeting are requested to register at *http://www.team-psa.com/niosh-OESSM07/home.asp* no later than November 1, 2007. Unreserved walk-in attendees will be accommodated on the day of the meeting if space is available.

The meeting has several scheduled presentations and panels that will include time for questions and answers. In addition, two breakout sessions will be held to solicit discussion and input on specific occupational exposure issues.

Presentations, questions, and oral comments given at the meeting will be recorded and included in the docket. Written comments will also be accepted at the meeting. Written comments may also be submitted to Diane Miller, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS C–34, Cincinnati, Ohio 45226, telephone 513/533–8611. All material submitted to the Agency should reference docket number NIOSH–091 and must be submitted by November 30, 2007 to be considered by the Agency. All electronic comments should be formatted as Microsoft Word. Please make reference to docket number NIOSH–091.

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, relevant to the current practice, limitations, and needs for development of occupational exposure assessment practices and policies.

NIOSH will use this information to assess the needs and scientific basis for revisions to its guidance and recommendations in occupational exposure assessment.

Contact Person for Technical Information: Paul Middendorf, telephone (513)533–8606, M/S C–9, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Contact Person for Submitting Comments/Meeting Attendance: Diane Miller, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS C–34, Cincinnati, Ohio 45226, telephone 513/533–8611. All material submitted to the Agency should reference docket number NIOSH–091.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Dated: October 18, 2007.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–21078 Filed 10–25–07; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–2088–92 and CMS–10244]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Agency: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Outpatient Rehabilitation Provider Cost Report; *Use:* In accordance with sections 1815(a), 1833(e) and 1861(v)(1)(A)(ii) of the Social Security Act, providers of service in the Medicare program are required to submit annual information to achieve reimbursement for health care services rendered to Medicare beneficiaries. Section 42 CFR 413.20(b) requires that cost reports be required from providers on an annual basis. Such cost reports are required to be filed with the provider's fiscal intermediary. The CMS 2088–92 cost report is needed to determine the amount of reimbursable cost that is due these providers for furnishing medical services to Medicare beneficiaries. *Form Number:* CMS–2088–92 (OMB#: 0938–0037); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 623; *Total Annual Responses:* 623; *Total Annual Hours:* 62,300.

2. *Type of Information Collection Request:* New Collection; *Title of*

Information Collection: Medicaid State Program Integrity Assessment (SPIA); *Use:* Under the provisions of the Deficit Reduction Act (DRA) of 2005, Congress directed CMS to establish the Medicaid Integrity Program (MIP), CMS' first national strategy to combat Medicaid fraud, waste, and abuse. CMS has two broad responsibilities under the MIP:

(1) Reviewing the actions of individuals or entities providing services or furnishing items under Medicaid; conducting audits of claims submitted for payment; identifying overpayments; and educating providers and others on payment integrity and quality of care; and

(2) Providing effective support and assistance to States to combat Medicaid fraud, waste, and abuse.

In order to fulfill the second of these requirements, CMS plans to develop a Medicaid State Program Integrity Assessment (SPIA) system. CMS is seeking approval from the Office of Management and Budget (OMB) to collect information from the States on an annual basis for input into a national SPIA system. Through the SPIA system, CMS will identify current Medicaid program integrity (PI) information, develop profiles for each State based on these data, determine areas to provide States with technical support and assistance, and use the data to develop performance measures to assess States' performance in an ongoing manner. Based on comments received during the 60-day comment period, we revised the supporting statement timeline and the instrument (Appendix B). In addition, we added a draft MIP glossary (Appendix C); *Form Number:* CMS–10244 (OMB#: 0938–NEW); *Frequency:* Reporting: Yearly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,400.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on November 26, 2007:

OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974

Dated: October 19, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–21116 Filed 10–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–262 and CMS–10142]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* CY 2009 Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations are required to submit plan benefit packages for all Medicare beneficiaries residing in their service area. The plan benefit package submission consists of the formulary file, Plan Benefit Package (PBP) software, and supporting documentation as necessary. MA and PDP organizations will generate a formulary to illustrate their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. Additionally, the PBP software will be used to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. CMS uses the formulary and PBP data to review and approve the plan benefit packages proposed by each MA and PDP organization.

CMS requires that MA and PDP organizations submit a completed formulary and PBP as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval. Based on operational changes and policy clarifications to the Medicare program and continued input and feedback by the industry, CMS has made the necessary changes to the plan benefit package submission. *Form Number:* CMS–R–262 (OMB#: 0938–0763); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 475 *Total Annual Responses:* 4987.5; Total Annual Hours: 11,400.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDPs); *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization (MMA), Medicare Advantage organizations (MAO) and Prescription Drug Plans (PDP) are required to submit an actuarial pricing ''bid'' for each plan offered to Medicare beneficiaries. CMS requires that MAOs and PDPs complete the BPT as part of the annual bidding process. During this process, organizations prepare their proposed actuarial bid pricing for the upcoming contract year and submit them to CMS for review and approval. The purpose of the BPT is to collect the actuarial pricing information for each plan. The BPT calculates the plan's bid, enrollee premiums, and payment rates. Refer to ''Attachment C'' for a summary of changes. *Form Number:* CMS–10142 (OMB#: 0938–0944); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 550 *Total Annual Responses:* 6,050; *Total Annual Hours:* 42,350.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections

referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on December 26, 2007:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L Harkless, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: October 19, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–21123 Filed 10–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–2276–PN]

Medicare and Medicaid Programs; Application by the Community Health Accreditation Program for Continued Deeming Authority for Home Health Agencies

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice with comment period acknowledges the receipt of a deeming application from the Community Health Accreditation Program for continued recognition as a national accrediting organization for home health agencies that wish to participate in the Medicare or Medicaid programs. Section 1865(b)(3)(A) of the Social Security Act requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 26, 2007.

ADDRESSES: In commenting, please refer to file code CMS–2276–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking*. Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2276–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2276–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310. Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed notice to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–2276–PN and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking*. Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a home health agency (HHA) provided certain requirements are met. Sections 1861(m) and (o), and 1891 of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as an HHA. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 484 specify the conditions that an HHA must meet in order to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for Home Health Care.

Generally, in order to enter into a provider agreement with the Medicare program, an HHA must first be certified by a State survey agency as complying

with the conditions or requirements set forth in part 484 of our CMS regulations. Thereafter, the HHA is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for deeming authority under part 488, subpart A must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the reapproval of accrediting organizations are set forth at §§ 488.4 and 488.8(d)(3). The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued deeming authority every six years or sooner as determined by us.

Community Health Accreditation Program's (CHAP's) term of approval as a recognized accreditation program for HHA's expires March 31, 2008.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and reapproval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of CHAP's request for continued deeming authority for HHAs. This notice also solicits public comment on whether CHAP's requirements meet or exceed the Medicare conditions for participation for HHAs.

III. Evaluation of Deeming Authority Request

CHAP submitted all the necessary materials to enable us to make a determination concerning its request for reapproval as a deeming organization for HHAs. This application was determined to be complete on September 3, 2007. Under section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of CHAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of CHAP's standards for an HHA as compared with CMS' HHA conditions of participation.
- CHAP's survey process to determine the following:

—The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

—The comparability of CHAP's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

—CHAP's processes and procedures for monitoring HHAs found out of compliance with CHAP's program requirements. These monitoring procedures are used only when CHAP identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).

—CHAP's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

—CHAP's capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.

—The adequacy of CHAP's staff and other resources, and its financial viability.

—CHAP's capacity to adequately fund required surveys.

—CHAP's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

—CHAP's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 5, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–20574 Filed 10–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–2277–PN]

Medicare and Medicaid Programs; Application by The Joint Commission for Continued Deeming Authority for Home Health Agencies

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice with comment period acknowledges the receipt of a deeming application from The Joint Commission for continued recognition as a national accrediting organization for home health agencies that wish to participate in the Medicare or Medicaid programs. Section 1865(b)(3)(A) of the Social Security Act requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 26, 2007.

ADDRESSES: In commenting, please refer to file code CMS–2277–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2277–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2277–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310. Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed notice to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–2277–PN and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a home health agency (HHA) provided certain requirements are met. Sections 1861(m) and (o), and 1891 of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as an HHA. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 484 specify the conditions that an HHA must meet in order to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for home health care.

Generally, in order to enter into a provider agreement with the Medicare program, an HHA must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 484 of our regulations. Thereafter, the HHA is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for deeming authority under part 488, subpart A must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as

stringent as the Medicare conditions. Our regulations concerning the reapproval of accrediting organizations are set forth at §§ 488.4 and 488.8(d)(3). The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued deeming authority every six years or sooner as determined by us.

The Joint Commission's term of approval as a recognized accreditation program for HHAs expires March 31, 2008.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and reapproval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of The Joint Commission's request for continued deeming authority for HHAs. This notice also solicits public comment on whether The Joint Commission's requirements meet or exceed the Medicare conditions for participation for HHAs.

III. Evaluation of Deeming Authority Request

The Joint Commission submitted all the necessary materials to enable us to make a determination concerning its request for reapproval as a deeming organization for HHAs. This application was determined to be complete on September 3, 2007. Under section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of The Joint Commission will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of The Joint Commission standards for an HHA as compared with CMS' HHA conditions of participation.
- The Joint Commission's survey process to determine the following:

—The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

—The comparability of The Joint Commission's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

—The Joint Commission's processes and procedures for monitoring HHAs found out of compliance with The Joint Commission program requirements. These monitoring procedures are used only when The Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).

—The Joint Commission's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

—The Joint Commission's capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.

—The adequacy of The Joint Commission's staff and other resources, and its financial viability.

—The Joint Commission's capacity to adequately fund required surveys.

—The Joint Commission's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

—The Joint Commission's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 5, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–20579 Filed 10–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3181–FN]

Medicare Program: Approval of Application by the American Diabetes Association (ADA) for Continued Recognition as a National Accreditation Organization That Accredits Entities To Furnish Outpatient Diabetes Self-Management Training

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces the approval of the American Diabetes Association (ADA) as a national accreditation organization for the purpose of determining that an entity meets the necessary quality standards to furnish outpatient diabetes self-management training services under Part B of the Medicare program.

Therefore, diabetes self-management training (DSMT) programs accredited by the ADA will receive deemed status under the Medicare program.

DATES: *Effective Date:* This accreditation is effective on October 27, 2007.

FOR FURTHER INFORMATION CONTACT: Joan A. Brooks, (410) 786–5526.

SUPPLEMENTARY INFORMATION:

I. Background

To participate in the Medicare program, diabetes self-management training (DSMT) programs must meet conditions for coverage specified in our regulations at 42 CFR part 410, subpart H. One requirement is that entities must satisfy required quality standards. Currently, one way of satisfying the quality standards under § 410.145 is to be approved by an approved accrediting body. The regulations pertaining to the application procedures for national accreditation organizations for DSMT are at § 410.142. After we approve and recognize the accreditation organization, it may accredit an entity to meet one of the sets of quality standards described in § 410.144.

II. Review Process

In evaluating an application from an accrediting organization, we consider the following factors under section 1865(b)(2) of the Social Security Act (the Act):

- Accreditation requirements.
- Survey procedures.
- Ability to provide adequate resources for conducting required surveys and to supply information for use in enforcement activities.
- Monitoring procedures.
- Ability to provide us with the necessary data for validation.

We are required by § 410.142(d) to publish a proposed notice in the **Federal Register** after the receipt of a written request for approval from a national accreditation organization. After review of the national accreditation organization's application, the regulations require that we publish a notice of our approval or disapproval after we receive a complete package of the information and the organization's deeming application.

III. Analysis of and Responses to Public Comments and Provisions of the Final Notice

We received a complete application from the American Diabetes Association (ADA) on March 3, 2007. On May 25, 2007, we published a proposed notice in the **Federal Register**, (72 FR 29325) announcing the application of the ADA for continued approval as an accreditation organization for diabetes self-management training programs.

Comment: We received one comment on our proposed notice, which was supportive of the ADA's application. Although the comment supported ADA, the commenter expressed concern that some of ADA's accrediting requirements do not reflect the current state of health care practice for many DSMT programs. Specifically, the commenter expressed concern about the requirements pertaining to data collection, documentation, location requirements, and fees. The commenter stated that accreditation requirements can be burdensome for small DSMT practices that may operate outside of a large hospital-based setting. The commenter further specified that some large hospitals' DSMT programs have closed in recent years, due to a variety of factors that include the burdensome administrative requirements of accreditation combined with overall low reimbursement for DSMT services.

Response: Although reimbursement issues are not within the scope of this final notice, we recognize these are issues of concern. Some reimbursement issues associated with DMST are—

- Entities' failure to meet the required number of participants for group training;
- Entities' failure to meet the requirement for both a registered dietician (RD) and a registered nurse (RN) on the training team; and
- Entities' failure to bill correctly.

Recent revisions made to the National Standards for Diabetes Self-Management Education Programs (NSDSMEP) include: 1) a reduction in the number of participants required for group training (from 15 to 10); and 2) a change in the instructional requirements that DSMT programs must meet. Previously, a DSMT entity was required to have both a RD and a RN conduct training. The recent revisions to the NSDSMEP changed this requirement. An entity may now have either a RD or a RN conduct training. This revision should help to alleviate some of the administrative burdens faced by entities when administering the DSMT benefit. Additionally, we have revised Chapter 18 of the CMS Claims Processing Manual, and Chapter 15 of the CMS Benefits Policy Manual to clarify the instructions for filing specific claims. Our findings indicate that the ADA continues to use one of the sets of quality standards described in § 410.144. It also continues to meet the CMS criteria as ''a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes'' to accredit entities to furnish training as specified in § 410.142(a).

The ADA began its Education Recognition Program (ERP) in 1986. At that time they formally recognized diabetes self-management education programs that meet the NSDSMEP. These standards, created by the National Diabetes Advisory Board (NDAB), were designed to promote quality diabetes self-management education nationwide for every person with diabetes.

A Task Force consisting of the ADA, the American Association of Diabetes Educators, the American Dietetic Association, the Veteran's Health Service, the National Certification Board for Diabetes Educators, the Centers for Disease Control and Prevention, the Department of Veterans Affairs, the Diabetes Research and Training Centers, the Indian Health Service, and the National Certification Board for Diabetes Educators was convened on March 31, 2006 and again on September 19, 2006 as part of the update process. The revised standards were approved on March 25, 2007 and was published in the June 2007 issue of Diabetes Care, Volume 30, Number 6. The task force reviewed the standards for their appropriateness, relevancy, scientific basis, specificity, and ability to be implemented in multiple settings. The current NSDSMEP standards (7th Edition) were effectuated in June 2007 and reflect the changing approaches in diabetes training and education.

We reviewed ADA's materials and the findings presented by the Iowa Foundation for Medicare Care (IFMC, Contract #GS–35F–5831 H/HHDM 500–2006–0015IG), which was under contract with CMS to validate ADA's accreditation policies. IFMC surveyed a sample of ADA's accredited facilities. Based on these reviews, we have determined that the ADA's deeming authority has been exercised in compliance with § 410.142. Therefore, ADA's continued recognition as a national accrediting organization is approved and is effective for 6 years, beginning October 27, 2007.

Authority: Sections 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Program No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: September 6, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–20495 Filed 10–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1389–N]

Medicare Program; Meeting of the Practicing Physicians Advisory Council, December 3, 2007

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a quarterly meeting of the Practicing Physicians Advisory Council (the Council). The Council will meet to discuss certain proposed changes in regulations and manual instructions related to physicians' services, as identified by the Secretary of Health and Human Services (the Secretary). This meeting is open to the public.

DATES: *Meeting Date:* Monday, December 3, 2007, from 8:30 a.m. to 5 p.m., e.s.t.

Deadline for Registration without Oral Presentation: Thursday, November 29, 2007, 12 noon, e.s.t.

Deadline for Registration with Oral Presentations: Friday, November 16, 2007, 12 noon, e.s.t.

Deadline for Submission of Oral Remarks and Written Comments: Wednesday, November 21, 2007, 12 noon, e.s.t.

Deadline for Requesting Special Accommodations: Monday, November 26, 2007, 12 noon, e.s.t.

ADDRESSES:

Meeting Location: The meeting will be held in Room 705A in the Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Submission of Testimony: Testimonies should be mailed to Kelly Buchanan, Designated Federal Official (DFO), Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Mail stop C4–13–07, Baltimore, MD 21244–1850, or contact the DFO via e-mail at *PPAC@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Kelly Buchanan, DFO, (410) 786–6132, or e-mail *PPAC@cms.hhs.gov.* News media representatives must contact the CMS Press Office, (202) 690–6145. Please refer to the CMS Advisory Committees' Information Line (1–877–449–5659 toll free), (410) 786–9379 local) or the Internet at *http://www.cms.hhs.gov/home/regsguidance.asp* for additional information and updates on committee activities.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces the quarterly meeting of the Practicing Physicians Advisory Council (the Council). The Secretary is mandated by section 1868(a)(1) of the Social Security Act (the Act) to appoint a Practicing Physicians Advisory Council based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the Council's consultation must occur before **Federal Register** publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) not later than December 31 of each year.

The Council consists of 15 physicians, including the Chair. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members of the Council must be physicians as described in section 1861(r)(1) of the Act; that is, State-licensed doctors of medicine or osteopathy. The remaining 4 members may include dentists, podiatrists, optometrists, and chiropractors. Members serve for overlapping 4-year terms.

Section 1868(a)(2) of the Act provides that the Council meet quarterly to discuss certain proposed changes in regulations and manual issuances that relate to physicians' services, identified by the Secretary. Section 1868(a)(3) of the Act provides for payment of expenses and per diem for Council members in the same manner as members of other advisory committees appointed by the Secretary. In addition to making these payments, the Department of Health and Human Services and CMS provide management and support services to the Council. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs in a manner to ensure appropriate balance of the Council's membership.

The Council held its first meeting on May 11, 1992. The current members are: Anthony Senagore, M.D., Chairperson; Jose Azocar, M.D.; M. Leroy Sprang, M.D.; Karen S. Williams, M.D.; Peter Grimm, D.O.; Jonathon E. Siff, M.D., MBA; John E. Arradondo, M.D., MPH; Helena Wachslicht Rodbard, M.D.; Vincent J. Bufalino, M.D.; Tye J. Ouzounian, M.D.; Geraldine O'Shea, D.O.; Arthur D. Snow, Jr., M.D.; Gregory J. Przybylski, M.D.; Jeffrey A. Ross, DPM, M.D.; and Roger L. Jordan, O.D.

II. Meeting Format and Agenda

The meeting will commence with the Council's Executive Director providing a status report, and the CMS responses to the recommendations made by the Council at the August 27, 2007 meeting, as well as prior meeting recommendations. Additionally, an update will be provided on the Physician Regulatory Issues Team. In accordance with the Council charter, we are requesting assistance with the following agenda topics:

- Stark Update.
- Overview of Medicare Demonstration Projects.
- Physician Fee Schedule Final Rule.
- Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) Final Rule.
- 9th Scope of Work/Quality Improvement Organization (QIO) Program.

For additional information and clarification on these topics, contact the DFO as provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual physicians or medical organizations that represent physicians wishing to present a 5-minute oral testimony on agenda issues must register with the DFO by the date listed in the **DATES** section of this notice. Testimony is limited to agenda topics only. The number of oral testimonies may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to the DFO for distribution to Council members for review before the meeting by the date listed in the **DATES** section of this notice. Physicians and medical organizations not scheduled to speak may also submit written comments to the DFO for distribution by the date listed in the **DATES** section of this notice.

III. Meeting Registration and Security Information

The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting the DFO at the address listed in the **ADDRESSES** section of this notice or by telephone at (410) 786–6132 by the date specified in the **DATES** section of this notice.

Since this meeting will be held in a Federal Government Building, the Hubert H. Humphrey Building, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. To gain access to the building, participants will be required to show a government-issued photo identification (for example, driver's license or passport), and must be listed on an approved security list before persons are permitted entrance. Persons not registered in advance will not be permitted into the Hubert H. Humphrey Building and will not be permitted to attend the Council meeting.

All persons entering the building must pass through a metal detector. In addition, all items brought to the Hubert H. Humphrey Building, whether personal or for the purpose of presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the DFO via the contact information specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

Authority: (Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a)).)

Dated: October 5, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–20484 Filed 10–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7006–N]

Medicare Program; Announcement of Meeting of the Advisory Panel on Medicare Education, December 4, 2007

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, section 10(a) (Pub. L. 92–463), this notice announces a meeting of the Panel on December 4, 2007. The Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. This meeting is open to the public.

DATES: *Meeting Date:* December 4, 2007 from 9 a.m. to 3:30 p.m., e.d.t.

Deadline for Meeting Registration, Presentations, and Comments: November 27, 2007, 12 noon, e.d.t.

Deadline for Requesting Special Accommodations: November 19, 2007, 12 noon, e.d.t.

ADDRESSES: *Meeting Location:* Doubletree Hotel 1515 Rhode Island Avenue, NW., Washington, DC 20005, (202) 232–7000.

Meeting Registration, Presentations, and Written Comments: Lynne Johnson, Designated Federal Official, Division of Forum and Conference Development, Office of External Affairs, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1–05–06, Baltimore, MD 21244–1850 or contact Ms. Johnson via e-mail at *Lynne.Johnson@cms.hhs.gov.*

Registration: The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting Lynne Johnson at the address listed in the **ADDRESSES** section of this notice or by telephone at (410) 786–0090, by 12 noon, e.d.t., on November 27, 2007.

FOR FURTHER INFORMATION CONTACT: Lynne Johnson, (410) 786–0090. Please refer to the CMS Advisory Committees' Information Line (1–877–449–5659 toll free)/(410–786–9379 local) or the Internet (*http://www.cms.hhs.gov/FACA/04_APME.asp*) for additional information and updates on committee activities. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION: Section 9(a)(2) of the Federal Advisory Committee Act authorizes the Secretary to establish an advisory panel if the Secretary determines that the panel is ''in the public interest in connection with the performance of duties imposed * * * by law.'' Such duties are imposed by section 1804 of the Social Security Act (the Act), requiring the Secretary to provide informational materials to Medicare beneficiaries about the Medicare program, and section 1851(d) of the Act, requiring the Secretary to provide for ''activities * * * to broadly disseminate information to medicare beneficiaries * * * on the coverage options provided under [Medicare Advantage] in order to promote an active, informed selection among such options.''

The Advisory Panel is also authorized by 1114(f) of the Social Security Act, 42 U.S.C. 1311(f), and section 222 of the Public Health Service Act, 42 U.S.C. 217a. The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7899) and approved the renewal of the charter on November 14, 2006. The establishment of the charter and the renewal of the charter were announced in the February 17, 1999 **Federal Register** (64 FR 7899), and the March 23, 2007 **Federal Register** (72 FR 13796), respectively. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

The goals of the Panel are as follows:

- To develop and implement a national Medicare education program that describes the options for selecting a health plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- To expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Anita B. Boles, Independent Consultant, Health Communications; Gwendolyn T. Bronson, SHINE/SHIP Counselor, Massachusetts SHINE Program; Dr. Yanira Cruz, President and Chief Executive Officer, National Hispanic Council on Aging; Clayton Fong, President and Chief Executive Officer, National Asian Pacific Center on Aging; Nan Kirsten-Forte, Executive Vice President, Consumer Services, WebMD; Dr. Jessie C. Gruman, President and Chief Executive Officer, Center for the Advancement of Health; Dr. David Lansky, Director, Health Program, Markle Foundation; Dr. Daniel Lyons, Senior Vice President, Government Programs, Independence Blue Cross; Dr. Frank B. McArdle, Manager, Hewitt Research Office, Hewitt Associates; Traci McClellan, J.D., Executive Director, National Indian Council on Aging; Dr. Keith Mueller, Professor and

Section Head, Health Services Research and Rural Health Policy, University of Nebraska; Lee Partridge, Senior Health Policy Advisor, National Partnership for Women and Families; Rebecca Snead, Executive Vice President/Chief Executive Officer, National Alliance of State Pharmacy Associations; William A. Steel, President, The National Grange; Marvin Tuttle, Jr., CAE, Executive Director and Chief Executive Officer, Financial Planning Association; Catherine Valenti, Chairperson and Chief Executive Officer, Caring Voice Coalition; and Grant Wedner, Vice President, Partnerships and Corporate Development, Daily Strength, Inc.

The agenda for the December 4, 2007 meeting will include the following:

- Recap of the previous (September 20, 2007) meeting.
- Medicare Enrollment, Outreach, Education, and Partnering Activities Update.
- Public Comment.
- Listening Session with CMS Leadership.
- Next Steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to Lynne Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Individuals requiring sign language interpretation or other special accommodations should contact Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 19, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–21080 Filed 10–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0205]

Exocrine Pancreatic Insufficiency Drug Products; Extension to Obtain Marketing Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it intends to continue to exercise enforcement discretion to ensure the continued availability of exocrine pancreatic insufficiency drug products after April 28, 2008. FDA intends to exercise its enforcement discretion with respect to unapproved pancreatic enzyme drug products until April 28, 2010, if the manufacturers have investigational new drug applications (INDs) on active status on or before April 28, 2008, and have submitted new drug applications (NDAs) on or before April 28, 2009. FDA is granting this extension to ensure the availability of exocrine pancreatic insufficiency drug products during the additional time needed by manufacturers to obtain marketing approval.

DATES: The period during which FDA intends to exercise its enforcement discretion against unapproved pancreatic insufficiency drug products is extended to April 28, 2010, if the manufacturer has an active IND on or before April 28, 2008, and has submitted an NDA on or before April 28, 2009.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 28, 2004 (69 FR 23410) (the 2004 notice), FDA announced that all exocrine pancreatic insufficiency drug products are new drugs and announced the conditions for continued marketing of the drug products. The 2004 notice covered pancreatic enzyme preparations containing the ingredients pancreatin and pancrelipase. Both ingredients are extracted mainly from hog pancreas and contain principally the enzymes amylase, protease, and lipase. Pancreatic extract drug products are indicated as replacement therapy to treat conditions associated with exocrine pancreatic insufficiency, including cystic fibrosis, chronic pancreatitis, pancreatic tumors, or pancreatectomy.

Pancreatic extract drug products have been marketed in the United States for many years. Marketing of some versions of these products predates the 1938 passage of the Federal Food, Drug, and Cosmetic Act (the act). Over the years, other pancreatic extract drug products have entered the market. Various dosage forms of pancreatic enzyme drug products are currently marketed as prescription drug products: Uncoated tablets, powders, capsules, enteric-coated tablets, and encapsulated enteric-coated microspheres.

Some pancreatic extract drug products were marketed over-the-counter (OTC). As part of the OTC drug review, FDA evaluated the safety and effectiveness of drug products used to treat exocrine pancreatic insufficiency. FDA's review of data and information on pancreatic extract drug products found significant variations in bioavailability among the various dosage forms and among products from different manufacturers of the same dosage form. Available data have shown that the formulation, dosage, and manufacturing process of pancreatic enzyme drug products have a critical effect on the safe and effective use of these drugs. FDA concluded that preclearance of each product to standardize enzyme bioactivity would be necessary. FDA also determined that continuous physician monitoring of patients is a collateral measure necessary to the safe and effective use of pancreatic enzyme drug products, requiring that these products be available by prescription only and that the products be approved through the new drug approval process to standardize enzyme activity (56 FR 32282, July 15, 1991; 60 FR 20162, April 24, 1995).

The 2004 notice reiterated FDA's determination that all pancreatic extract drug products are new drugs under section 201(p) of the act (21 U.S.C. 321(p)), requiring approved NDAs under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314. The document stated that FDA expects to receive only NDAs, including applications submitted under section 505(b)(2) of the act, for these products. To assist manufacturers of pancreatic extract drug products in preparing and submitting documentation to meet NDA requirements for the drug products, FDA announced the availability of a draft guidance for industry entitled ''Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs'' in the **Federal Register** of April 28, 2004 (69

FR 23414). In response, FDA received a number of comments which the agency considered in finalizing the guidance. In the **Federal Register** of April 14, 2006 (71 FR 19524), FDA announced the availability of the final guidance (available on the Internet at *http://www.fda.gov/cder/guidance/index.htm*).

FDA stated in the 2004 notice that pancreatic extract drug products are used to treat exocrine pancreatic insufficiency, a condition in which symptoms are due to deficient secretion of pancreatic enzymes (i.e., lipase, protease, amylase) essential for normal digestion and absorption, and no alternative drug is relied upon by the medical community to treat the lack of lipase, protease, and amylase caused by exocrine pancreatic insufficiency. The severity of the conditions varies from patient to patient as does the dosage requirement of pancreatic enzyme replacement therapy needed to relieve the symptoms of pancreatic insufficiency.

Pancreatic enzyme therapy is a daily requirement for patients with exocrine pancreatic insufficiency and is needed for survival for many of these patients (e.g., cystic fibrosis patients). The appropriate daily dose of pancreatic enzymes must be individualized and adjusted when clinically indicated. To meet the needs of patients requiring pancreatic enzyme replacement therapy, drug products with varying dosage forms, enzyme content, and activity need to remain available for patient use. Only one product, Cotazym, sponsored by Organon, Inc., is the subject of an approved NDA and that product is not currently being marketed.

The 2004 notice advised that FDA intended to exercise its enforcement discretion until April 28, 2008, as to unapproved pancreatic enzyme drug products that were marketed on or before April 28, 2004. FDA determined that pancreatic enzyme drug products are medically necessary and, accordingly, FDA intended to exercise its enforcement discretion so that pancreatic extract drug products would remain available during the period necessary for manufacturers to conduct the required studies, prepare applications, and have the applications approved.

This provision for the exercise of enforcement discretion applied only to pancreatic enzyme products marketed on or before the publication of the April 28, 2004, **Federal Register** document. The document stated that after April 28, 2008, any pancreatic enzyme drug product that is introduced or delivered for introduction into interstate commerce without an approved application will be subject to regulatory action, unless there has been a finding by FDA under a citizen petition submitted for that product that the product is not subject to the new drug requirements of the act. The deadline for filing a citizen petition was June 28, 2004. No one submitted a citizen petition in response to the 2004 notice.

In response to the 2004 notice, a number of manufacturers of pancreatic extract drug products have indicated that they need an extension of time to obtain approved applications. The manufacturers contend that additional time is needed because of numerous problems encountered during the drug development process, predominantly manufacturing issues, and difficulty conducting all of the required studies needed for NDA filing and approval.

The agency has carefully considered the requests and concludes that additional time is justified to ensure the continued availability of pancreatic extract drug products after April 28, 2008. As these pancreatic extract drugs are naturally-derived products of porcine origin, manufacturers must conform with currently accepted standards for protein therapeutic products. The justification for this extension is based upon chemistry, manufacturing, and control issues that previously have not been well-understood and have been found to be particularly challenging for these enzyme preparations derived from porcine pancreas. These issues include the following:

- Control and evaluation of variability of pancreatic source materials used in drug substance manufacture;
- Measurement of viral loads, viral inactivation, and resultant risk assessment and mitigation strategies as described in International Conference on Harmonisation guidance Q5A;
- Development and implementation of validated purity and identity drug substance and product release and stability testing methodologies for the very complex protein mixtures derived from porcine pancreas;
- Required modification and validation of the traditional lipase potency assay methodology based upon recent scientific studies; and
- Maintenance and confirmation of drug product stability without the use of overages to increase the dating period.

By this notice, FDA is extending the period during which it intends to exercise its enforcement discretion as to certain unapproved pancreatic enzyme products until April 28, 2010.

This extension of the period during which FDA intends to exercise its enforcement discretion applies to any manufacturer of pancreatic extract drug products marketed on or before publication of the 2004 notice, if the manufacturer has an active IND for its pancreatic extract product on or before April 28, 2008, has submitted an NDA on or before April 28, 2009, and is pursuing approval of its application with due diligence as determined by FDA. In determining the due diligence of an applicant, FDA will examine the facts and circumstances of the applicant's actions during the drug development and review period to determine whether the applicant exhibited the degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, an applicant during this period. FDA will take into consideration whether the applicant is conducting its clinical trials in a manner and at a rate sufficient for NDA submission on or before April 28, 2009, the adequacy and completeness of any required or necessary documents submitted by the applicant to FDA, the speed and thoroughness with which the applicant responds to any FDA requests for information or notifications of deficiencies, and any other relevant evidence of whether the applicant is making a genuine effort to meet the deadlines set out in this notice and obtain FDA approval for its products.

FDA believes that establishing certain milestones will ensure that manufacturers are actively pursuing an NDA approval. Under those circumstances, extending the period of enforcement discretion as described in this notice will provide sufficient time for manufacturers to obtain approval of NDAs. Therefore, the agency does not anticipate that any further extensions will be needed. The agency, however, does not intend to exercise its enforcement discretion as described in this notice if the following conditions exist: (1) A person manufacturing or shipping an unapproved product covered by this notice is violating other provisions of the act or (2) there is significant new information related to a safety risk associated with a specific product covered by this notice.

FDA intends to take regulatory action, including but not limited to initiating seizure, injunction, or other judicial or administrative proceedings, against manufacturers that are marketing unapproved pancreatic insufficiency drug products and are not actively pursuing approval. Actively pursuing approval means that the manufacturer has an active IND on or before April 28, 2008, and has submitted an NDA on or

before April 28, 2009.[1] The agency may choose not to issue a warning letter or any further warning prior to taking a regulatory action against a firm that is marketing an unapproved exocrine pancreatic insufficiency drug product and not actively pursuing approval.

This notice is issued under sections 502 and 505 of the act (21 U.S.C. 352) and under authority delegated to the Assistant Commissioner for Policy.

Dated: October 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21082 Filed 10–25–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0364]

Draft Guidance for Industry and Food and Drug Administration Staff; Impact-Resistant Lenses: Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Impact-Resistant Lenses: Questions and Answers.'' This draft guidance document answers manufacturer, importer, and consumer questions on impact-resistant lenses, including questions on test procedures, lens testing apparatus, record maintenance, and exemptions to testing.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 24, 2008.

ADDRESSES: Submit written requests for single copies of the guidance document entitled''Impact-Resistant Lenses: Questions and Answers'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3150.

SUPPLEMENTARY INFORMATION:

I. Background

Eyeglasses and sunglasses are medical devices and are subject to device regulations, including § 801.410 (21 CFR 801.410). This draft guidance document revises the original guidance document entitled ''Impact-Resistant Lenses: Questions and Answers'' (FDA 87–4002), issued September 1987. This draft guidance document also contains detailed and updated discussions of the following: (1) Lens blanks; (2) semi-finished, finished, and plano lenses; and (3) import entry inspections.

To reduce the number of eye injuries, eyeglasses and sunglasses must be fitted with impact-resistant lenses capable of withstanding the impact test described under § 801.410(d)(2). This draft guidance answers questions for manufacturers, importers, and testing laboratories on such topics as test procedures, lens testing apparatus, record maintenance, and exemptions to testing.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on impact-resistant lenses. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Impact-Resistant Lenses: Questions and Answers,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (23) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 801.109 have been approved under OMB Control No. 0910–0485; the collections of information in 21 CFR 807.87 have been approved under OMB Control No. 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB Control No. 0910–0073.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy.

[1] If FDA decides to take enforcement action against a firm's unapproved exocrine pancreatic insufficiency drug product, the agency may at the same time take action relating to any and all of the firm's other violations. For example, if a firm continues to market an unapproved exocrine pancreatic insufficiency drug product but fails to actively pursue approval, to preserve limited agency resources, FDA may take enforcement action relating to any and all of the firm's other unapproved drugs that require applications (see, e.g., *United States* v. *Sage Pharmaceuticals*, 210 F. 3d 475, 479–480 (5th Cir. 2000) (permitting the agency to combine all violations of the act in one proceeding, rather than taking action against multiple violations of the act in ''piecemeal fashion'')).

Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21122 Filed 10–25–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; the Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 21, 2007, pages 46640–46641, and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance. *Type of Information Collection Request:* Renewal (OMB No. 0925–0493). *Need and Use of Information Collection:* This project identifies and quantifies factors associated with the presence and progression of subclinical cardiovascular disease (CVD)—that is, atherosclerosis and other forms of CVD that have not produced signs and symptoms. The findings provide important information on subclinical CVD in individuals of different ethnic backgrounds and provide information for studies on new interventions to prevent CVD. The aspects of the study that concern direct participant evaluation received a clinical exemption from OMB clearance (CE–99–11–08) in April 2000. OMB clearance is being sought for the contact of physicians and participant proxies to obtain information about clinical CVD events that participants experience during the follow-up period. *Frequency of Response:* The participants will be contacted annually. *Affected Public:* Individuals or households; Businesses or other for profit; Small businesses or organizations. *Type of Respondents:* Individuals or households; physicians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 550; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response:* .2; and *Estimated Total Annual Burden Hours Requested:* 36.7. The annualized cost to respondents is estimated at $5,595, assuming respondents time at the rate of $18.65 per hour and physician time at the rate of $75 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATES OF HOUR BURDEN

Type of respondent	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Physicians	250	1	0.20	16.7
Proxies	300	1	0.20	20
Total	550	1	0.20	36.7

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Jean Olson, Epidemiology Branch, Division of Prevention and Population Sciences, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, Suite 10018, MSC # 7936, Bethesda, MD, 20892–7936, or call 301–435–0397 (non-toll-free number), or e-mail your request, including your address to: *OlsonJ@nhlbi.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: October 16, 2007.

Mike Lauer,

Director, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.

Dated: October 18, 2007.

Suzanne Freeman,

OMB Clearance Officer, NHLBI, National Institutes of Health.

[FR Doc. E7–21103 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Cell-Nanofiber Composite Based Engineered Cartilage

Description of Invention: Available for licensing and commercial development is a tissue-engineered cartilage derived from a cellular composite made from a biodegradable, biocompatible polymeric nanofibrous matrix having dispersed chondrocytes or adult mesenchymal stem cells. More particularly, tissue-engineered cartilage can be prepared where the cartilage has a biodegradable and biocompatible nanofibrous polymer matrix prepared by electrospinning and a plurality of chondocytes or mesenchymal stem cells dispersed in the pores of the matrix. The tissue-engineered cartilage possesses compressive strength properties similar to natural cartilage.

The electrospinning process is a simple, economical means to produce biomaterial matrices or scaffolds of ultra-fine fibers derived from a variety of biodegradable polymers (Li WJ, *et al. J. Biomed. Mater. Res.* 2002; 60:613–21). Nanofibrous scaffolds (NFSs) formed by electrospinning, by virtue of structural similarity to natural extracellular matrix (ECM), may represent promising structures for tissue engineering applications. Electrospun three-dimensional NFSs are characterized by high porosity with a wide distribution of pore diameter, high-surface area to volume ratio and morphological similarities to natural collagen fibrils (Li WJ, *et al. J. Biomed. Mater. Res.* 2002; 60:613–21). These physical characteristics promote favorable biological responses of seeded cells in vitro and in vivo, including enhanced cell attachment, proliferation, maintenance of the chondrocytic phenotype (Li WJ, *et al. J. Biomed. Mater. Res.* 2003; 67A: 1105–14), and support of chondrogenic differentiation (Li WJ, *et al. Biomaterials* 2005; 26:599–609) as well as other connective tissue linage differentiation (Li WJ, *et al. Biomaterials* 2005; 26:5158–5166). The invention based on cell-nanofiber composite represents a candidate engineered tissue for cell-based approaches to cartilage repair.

Application: Cartilage repair and methods for making tissue-engineered cartilage.

Developmental Status: Electrospinning method is fully developed and cartilage has been synthesized.

Inventors: Wan-Ju Li and Rocky Tuan (NIAMS).

Publications: The invention is further described in:

1. W–J Li *et al.* Engineering controllable anisotropy in electrospun biodegradable nanofibrous scaffolds for musculoskeletal tissue engineering. J Biomech. 2007;40(8):1686–1693. Epub 2006 Oct 23, doi:10.1016/jbiomech.2006.09.004.

2. W–J Li *et al.* Fabrication and characterization of six electrospun poly(alpha-hydroxy ester)-based fibrous scaffolds for tissue engineering applications. Acta Biomater. 2006 Jul;2(4):377–385. Epub 2006 May 6, doi:10.1016/j.actbio.2006.02.005.

3. CK Kuo *et al.* Cartilage tissue engineering: its potential and uses. Curr Opin Rheumatol. 2006 Jan;18(1):64–73. Review.

4. W–J Li *et al.* Multilineage differentiation of human mesenchymal stem cells in a three-dimensional nanofibrous scaffold. Biomaterials. 2005 Sep;26(25):5158–5166.

Patent Status:

U.S. Provisional Application No. 60/690,998 filed 15 Jun 2005 (HHS Reference No. E–116–2005/0–US–01).

PCT Application No. PCT/US2006/0237477 filed 15 Jun 2006 (HHS Reference No. E–116–2005/0–PCT–02).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; soukasp@mail.nih.gov.

Cell-Nanofiber Composite and Cell-Nanofiber Composite Amalgam Based Engineered Intervertebral Disc

Description of Invention: Diseased or damaged musculoskeletal tissues are often replaced by an artificial material, cadaver tissue or donated, allogenic tissue. Tissue engineering offers an attractive alternative whereby a live, natural tissue is generated from a construct made up of a patient's own cells or an acceptable/compatible cell source in combination with a biodegradable scaffold for replacement of defective tissue.

Degeneration of the intervertebral disc (IVD) is a common and significant source of morbidity in our society. Approximately 8 of 10 adults at some point in their life will experience an episode of significant low back pain, with the majority improving without any formal treatment. However, for the subject requiring surgical management current interventions focus on fusion of the involved IVD levels, which eliminates pain but does not attempt to restore disc function. Approximately 200,000 spinal fusions were performed in the United States in 2002 to treat pain associated with lumbar disc degeneration. Spinal fusion however is thought to significantly alter the biomechanics of the disc and lead to further degeneration, or adjacent segment disease. Therefore, in the past decade there has been mounting interest in the concept of IVD replacement. The replacement of the IVD holds tremendous potential as an alternative to spinal fusion for the treatment of degenerative disc disease by offering a safer alternative to current spinal fusion practices.

At the present time, several disc replacement implants are at different stages of preclinical and clinical testing. These disc replacement technologies are designed to address flexion, extension, and lateral bending motions; however, they do little to address compressive forces and their longevity is limited due to their inability to biointegrate. Therefore, a cell-based tissue engineering approach offers the most promising alternative to replace the degenerated IVD. Current treatment for injuries that penetrate subchondral bone include subchondral drilling, periosteal tissue grafting, osteochondral allografting, chondrogenic cell and transplantation; but are limited due to suboptimal integration with host tissues.

The present invention claims tissue engineered intervertebral discs comprising a nanofibrous polymer hydrogel amalgam having cells dispersed therein, methods of fabricating tissue engineered intervertebral discs by culturing a mixture of stem cells or intervertebral disc cells and a electrospun nanofibrous polymer hydrogel amalgam in a suitable bioreactor, and methods of treatment comprising implantation of tissue engineered intervertebral disc into a subject.

Application: Intervertebral disc bio-constructs and electrospinning methods for fabrication of the discs.

Developmental Status: Prototype devices have been fabricated and preclinical studies have been performed.

Inventors: Wan-Ju Li, Leon Nesti, Rocky Tuan (NIAMS).

Patent Status:

U.S. Provisional Application No. 60/847,839 filed 27 Sep 2006 (HHS Reference No. E–309–2006/0–US–01).

U.S. Provisional Application No. 60/848,284 filed 28 Sep 2006 (HHS Reference No. E–309–2006/1–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

Bioreactor Device and Method and System for Fabricating Tissue

Description of Technology: Available for licensing and commercial development is a millifluidic bioreactor system for culturing, testing, and fabricating natural or engineered cells and tissues. The system consists of a millifluidic bioreactor device and methods for sample culture. Biologic samples that can be utilized include cells, scaffolds, tissue explants, and organoids. The system is microchip controlled and can be operated in closed-loop, providing controlled delivery of medium and biofactors in a sterile temperature regulated environment under tabletop or incubator use. Sample perfusion can be applied periodically or continuously, in a bidirectional or unidirectional manner, and medium re-circulated.

Advantages:

The device is small in size, and of conventional culture plate format.

Provides the ability to grow larger biologic samples than microfluidic systems, while utilizing smaller medium volumes than conventional bioreactors. The bioreactor culture chamber is adapted to contain sample volumes on a milliliter scale (10 [mu]L to 1 mL, with a preferred size of 100 [mu]L), significantly larger than chamber volumes in microfluidic systems (on the order of 1 [mu]L). Typical microfluidic systems are designed to culture cells and not larger tissue samples.

The integrated medium reservoirs and bioreactor chamber design provide for, (1) concentration of biofactors produced by the biologic sample, and (2) the use of smaller amounts of exogenous biofactor supplements in the culture medium. The local medium volume (within the vicinity of the sample) is less than twice the sample volume. The total medium volume utilized is small, preferably 2 ml, significantly smaller than conventional bioreactors (typically using 500–1000 mL).

Provides for real-time monitoring of sample growth and function in response to stimuli via an optical port and embedded sensors. The optical port provides for microscopy and spectroscopy measurements using transmitted, reflected, or emitted (e.g., fluorescent, chemiluminescent) light. The embedded sensors provide for measurement of culture fluid pressure and sample pH, oxygen tension, and temperature.

Capable of providing external stimulation to the biologic sample, including mechanical forces (e.g. fluid shear, hydrostatic pressure, matrix compression, microgravity via clinorotation), electrical fields (e.g., AC currents), and biofactors (e.g., growth factors, cytokines) while monitoring their effect in real-time via the embedded sensors, optical port, and medium sampling port.

Monitoring of biologic sample response to external stimulation can be performed non-invasively and non-destructively through the embedded sensors, optical port, and medium sampling port. Testing of tissue mechanical and electrical properties (e.g., stiffness, permeability, loss modulus via stress or creep test, electrical impedance) can be performed over time without removing the sample from the bioreactor device.

The bioreactor sample chamber can be constructed with multiple levels fed via separate perfusion circuits, facilitating the growth and production of multiphasic tissues.

Application: Cartilage repair and methods for making tissue-engineered cartilage.

Development Stage: Electrospinning method is fully developed and cartilage has been synthesized.

Inventors: Juan M. Taboas (NIAMS), Rocky S. Tuan (NIAMS), et al.

Patent Status:

U.S. Provisional Application No. 60/701,186 filed 20 Jul 2005 (HHS Reference No. E–042–2005/0–US–01).

PCT Application No. PCT/US2006/028417 filed 20 Jul 2006, which published as WO 2007/012071 on 25 Jan 2007 (HHS Reference No. E–042–2005/0–PCT–02).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

Dated: October 22, 2007.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E7–21100 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Public Teleconference Regarding Licensing and Collaborative Research Opportunities for: Treatment of Autoimmune and Allergic Disorders (NIAID)

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

Technology Summary

These technologies relate to compositions and methods useful in treating autoimmune diseases generally, and Multiple Sclerosis specifically.

Technology Description

Scientists at the NIH have discovered a method for the treatment or prevention of autoimmune diseases, allergic or atopic disorders, and graft rejections. This method selectively induces apoptosis of disease causing T lymphocytes, while sparing the majority of T-cells. Cell death is achieved by the cyclical administration of disease specific antigens and IL–2.

Further, the NIH scientists have developed compositions and methods for clinical assessment, diagnosis and treatment of Multiple Sclerosis (MS). The compositions are molecules related to the human proteolipid protein (PLP), and the 21.5 kDA fetal isoform of human myelin basic protein (MBP), including nucleic acids and polypeptides. The polypeptides can be used to assay T-cells for responsiveness to MBP and PLP epitopes. They are further useful as therapeutic agents for treating MS by inducing T-cell apoptosis. The inventors have demonstrated that treatment with MP4, a protein chimera of MBP, and a modified form of PLP, termed PLP4, prevented clinical symptoms of MS in both rodent and non-human primates. They have also completed primate toxicity tests demonstrating the compounds are non-toxic.

Novel application of these methods described in these technologies include:

Infusion of autoimmune disease antigen peptides reduces the severity of allergic diseases.

Pre-immunization prior to engraftment with foreign tissues prolongs graft survival time.

With molecular identification of allergy-evoking antigens, it will be possible to immunize in cycle with IL–4 to induce apoptosis of T cells involved in allergic disorders.

It is envisioned that autoimmune diseases such as multiple sclerosis, rheumatic fever, lupus and others can be treated using IL–2 and the relevant peptide to cause apoptosis of the T cells responsible for the disease.

The fact that interleukin-2 and 4 participates in the death of a subpopulation of T lymphocytes cells capable of causing diseases while leaving the majority of T lymphocyte cells substantially unaffected enhances the therapeutic value of these inventions.

The use of a novel therapeutic agent, i.e., MP4, in the treatment of MS.

Competitive Advantage of Our Technology

Autoimmune diseases result from a dysfunction of the immune system in which the body attacks its own organs, tissues and cells. More than 80 clinically distinct autoimmune diseases have been identified, including: type-1 diabetes (300,000–500,000 cases in the U.S.); systemic lupus erythematosus (240,000 cases in the U.S.); multiple sclerosis (250,000 to 350,000); rheumatoid arthritis (2.1 million cases in the U.S.); inflammatory bowel diseases, including both Crohn's disease and ulcerative colitis (800,000 in the U.S.); hemolytic anemia; Graves' disease; scleroderma; psoriasis (2% to 4% of the U.S. population); Sjörgen's syndrome, Immune Thrombocytopenic Purpura (ITP). Collectively, autoimmune diseases afflict 14–22 million Americans or 5% to 8% of the United States population.

Treatment of autoimmune diseases generally involves suppressing the immune system, and depending on the particular disease, different treatments are used. To demonstrate the diversity among these treatments consider the following: immunosuppressants such as azathioprine, chlorambucil, cyclophosphamide, cyclosporine or methostrexate are among the category of therapeutic agents employed in treating some autoimmune diseases. Corticosteroids such as prednisone are also used for both their immunosuppressive effect and anti-inflammatory activities. Tumor Necrosis Factor Antagonists, such as Etanercept and Infliximab are also used in treating some autoimmune disorders. Finally, Platelet transfusion and Plasmapheresis are used to treat a few autoimmune disorders.

MS is an autoimmune disease affecting the central nervous system, characterized by disseminated patches of demyelination in the brain and spinal cord, resulting in multiple and varied neurologic symptoms and signs, usually with remissions and exacerbations. The currently approved drugs for MS are different recombinant forms of interferons and are primarily used for the treatment of RRMS. Antegren, which blocks cellular adhesion, is currently in the pipeline and will be useful in treating SPMS patients.

There is a current theoretical patient population of approx 368,000 patients with MS in the U.S. and approx. 450,000 in Western Europe. Considering an estimated yearly growth rate of this market of 0.9%, this number will increase to approximately 390,000 by 2010 and approximately 400,000 by 2013 in the U.S. alone.

The total U.S. sales in 2003 for the top MS drugs, i.e., Rebif, Avonex, Betaseron, and Copaxone, was about $1.7 billion. However, within a six-month period, 6–10% of the patients have to discontinue interferon therapy. These patients are likely to switch to new therapies as they become available. Thus, this is the patient population that will benefit from the compositions discovered at the NIH, i.e., MP4 therapy.

Patent Estate

This technology consists of the following patents and patent applications:

1. U.S. Patent No. 6,083,503, entitled ''Interleukin-2 stimulated T lymphocyte cell death for the treatment of autoimmune diseases, allergic responses, and graft rejection'' (E–137–1991/0–US–03);

2. U.S. Patent No. 5,989,546, entitled ''Interleukin-2 stimulated T lymphocyte cell death for the treatment of allergic responses'' (E–137–1991/0–US–04);

3. U.S. Patent No. 5,935,575, entitled ''Interleukin-4 stimulated T lymphocyte cell death for the treatment of allergic disorders'' (E–151–1992/0–US–11);

4. U.S. Patent Application No. 08/431,644 entitled ''Modified Myelin Basic Protein Molecules'' (E–033–1996/0–US–01); and

5. U.S. Patent Application No. 08/482,114 entitled ''Modified Proteolipid Protein Molecules'' (E–128–1996/1–US–01).

Next Step: Teleconference

There will be a teleconference where the principal investigator will explain this technology. Licensing and collaborative research opportunities will also be discussed. If you are interested in participating in this teleconference please call or e-mail Mojdeh Bahar; (301) 435–2950; *baharm@mail.nih.gov.* OTT will then e-mail you the date, time and number for the teleconference.

Dated: October 22, 2007.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E7–21104 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative 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 Center for Complementary and Alternative Medicine Special Emphasis Panel, Developmental Center for Research on Complementary and Alternative Medicine.

Date: November 12–14, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Marriott at Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Martina Schmidt, PhD., Scientific Review Administrator, Office of Scientific Review, National Center for Complementary & Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301–594–3456, *schmidma@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Dated: October 22, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5310 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Aquatic Health SEP.

Date: November 19, 2007.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: 6701 Democracy Blvd., 1 Democracy Plaza, 1068, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: John R. Glowa, PhD, Scientific Review Administrator, National Center for Research Resources, or National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1078, MSC 4874, Bethesda, MD 20892–4874, (301) 435–0807, *glowaj@mail.nih.gov.*

Name of Committee: National Center for Research Resources Special Emphasis Panel EHP Contract.

Date: December 5, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Guo Zhang, MPH, PhD, MD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1064, Bethesda, MD 20892, (301) 435–0812, *zhanggu@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS).

Dated: October 22, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5313 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; K23 Conflict Review.

Date: November 6, 2007.

Time: 2:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Joann McConnell, Ph.D., Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, Msc 9529, Bethesda, MD 20892–9529, (301) 496–5324, *mcconnej@ninds.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Stroke Special Emphasis.

Date: November 16, 2007.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, Msc 9529, Bethesda, MD 20852, (301) 435–6033, *rajarams@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; T32 Applications.

Date: November 28, 2007.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue, NW., Washington, DC 20036.

Contact Person: Phillip F. Wiethorn, Scientific Review Administrator, DHHS/NIH/NINDS/DER/SRB, 6001 Executive Boulevard, Msc 9529, Neuroscience Center, Room 3203, Bethesda, MD 20892–9529, (301) 496–5388, *wiethorp@ninds.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 22, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5307 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIDA–K CONFLICTS SEP.

Date: November 15, 2007.

Time: 8 a.m. to 9 a.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Kristen V. Huntley, Ph.D., Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 435–1433, *huntleyk@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 24, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5308 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Training and Career Development Subcommittee, November 14, 2007, 9 a.m. to November 16, 2007, 5 p.m., Double Tree Hotel & Executive Meeting Center, 8120 Wisconsin Ave., Bethesda, MD 20814 which was published in the **Federal Register** on September 17, 2007, Volume 72, # 179.

The date of the meeting was changed to November 13–16, 2007. The meeting is closed to the public.

Dated: October 22, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5309 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Tularemia Immunology.

Date: November 14, 2007.

Time: 11 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817. (Telephone Conference Call)

Contact Person: Brenda Lange-Gustafson, Ph.D., Scientific Review Administrator, NIAID, DEA, Scientific Review Program, Room 3122, 6700B Rockledge Drive, MSC–7616, Bethesda, MD 20892–7616, 301–451–3684, *bgustafson@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS).

Dated: October 22, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5311 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, HIV-Associated Nephropathy.

Date: December 7, 2007.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Barbara A. Woynarowska, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 402–7172, *woynarowskab@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Organ Transplantation.

Date: December 11, 2007.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National INstitutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *Is38oz@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS).

Dated: October 22, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5312 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Interagency Autism Coordinating Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Date: November 30, 2007.

Time: 9 a.m. to 4 p.m.

Agenda: Introduction of members, discussion of strategic plan for Autism Spectrum Disorder research, and presentations.

Place: Ronald Reagan Building and International Trade Center, Rotunda, North Tower, 8th Floor, 1300 Pennsylvania Avenue, NW., Washington, DC 20004, Phone: 202–312–1300.

Contact Person: Takea Herbert, Interagency Autism Coordinating Committee, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 6187, MSC 9669, Bethesda, MD 20892–9669, (301) 443–7153, *herbertta@mail.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, all guests and vehicles are screened upon entry into the underground parking garage at the Ronald Reagan Building. Please allow extra time for this process.

A registration form and information about the meeting is available on this IACC Web site: *https://www.infinityconferences.com/InfiniBase/Registration/Reg.aspx?ptguid=1ed5d757–748f–4e23–9fd7–a00b765bf1c9.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS).

Dated: October 22, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5314 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Urogynecological Application.

Date: November 9, 2007.

Time: 4:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ryan G. Morris, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892, 301–435–1501, *morris@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Skeletal Biology Structure and Regeneration.

Date: November 13, 2007.

Time: 2:15 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: John P. Holden, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301–496–8551, *holdenjo@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular Signaling and Vascular Function.

Date: November 14, 2007.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Rajiv Kumar, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7802, Bethesda, MD 20892, 301–435–1212, *kumarra@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflicts: Skeletal Muscle and Exercise Physiology.

Date: November 14, 2007.

Time: 12 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: John P. Holden, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, (301) 496–8551, *holdenjo@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Knee Joint Degradation Assessment.

Date: November 15, 2007.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: John P. Holden, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301–496–8551, *holdenjo@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Hypertension and Renal Microcirculation.

Date: November 19, 2007.

Time: 1 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Anshumali Chaudhari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210, *chaudhaa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Ischemic Injury and Carioprotection.

Date: November 20, 2007.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Begthesda, MD, (Telephone Conference Call).

Contact Person: Rajiv Kumar, PhD, Scientific Review Administratoor, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7802, Bethesda, MD 20892, 301–435–1212, *kumarra@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Aspergillus Genetics and Genomics.

Date: December 4–5, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barbara J. Thomas, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2218, MSC 7890, Bethesda, MD 20892, 301–435–0603, *bthomas@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Opportunistic Infections and Malignancies in AIDS.

Date: December 4, 2007.

Time: 10:30 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Cofnerence Call).

Contact Person: Mary Clare Walker, PhD, Scientific Review Administrator, Center for Scientific Review, Natinal Institutes of

health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.3065, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 22, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5306 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Determination Pursuant to Section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 as Amended by Section 102 of the REAL ID Act of 2005 and as Amended by the Secure Fence Act of 2006

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice of determination.

SUMMARY: The Secretary of Homeland Security has determined, pursuant to law, that it is necessary to waive certain laws, regulations and other legal requirements in order to ensure the expeditious construction of physical barriers and roads in the vicinity of the international land border of the United States in Arizona.

DATES: This Notice is effective on October 26, 2007.

Determination and Waiver

In section 102(a) of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Public Law 104–208, Div. C, 110 Stat. 3009–546, 3009–554 (Sept. 30, 1996) (IIRIRA) (8 U.S.C. 1103 note (2000)), Congress provided that the Attorney General shall take such actions as may be necessary to install additional physical barriers and roads (including the removal of obstacles to detection of illegal entrants) in the vicinity of the United States border to deter illegal crossings in areas of high illegal entry into the United States. Pursuant to sections 1511 and 1517 of the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, 2309, 2311 (Nov. 25, 2002) (HSA) (6 U.S.C. 551, 557), the authorities of the Attorney General contained in section 102 of the IIRIRA were transferred to me. In section 102(c) of the IIRIRA, as amended by section 102 of the REAL ID Act of 2005, Public Law 109–13, Div. B, 119 Stat. 231, 302, 306 (May 11, 2005) (REAL ID Act) (8 U.S.C. 1103 note), Congress granted to me the authority to waive all legal requirements that I, in my sole discretion, determine necessary to ensure the expeditious construction of barriers and roads under section 102 of IIRIRA.

I determine that the area in the vicinity of the United States border from approximately 4.75 miles west of the Naco, Arizona Port of Entry to the western boundary of the San Pedro Riparian National Conservation Area (SPRNCA) in southeastern Arizona including the lands covered by the Temporary Restraining Order (TRO) signed by Judge Ellen S. Huvelle on October 10, 2007, in the case of *Defenders of Wildlife et al.* v. *Bureau of Land Management et al.*, Case 1:07–cv–01801–ESH, is an area of high illegal entry. There is presently a need to construct fixed and mobile barriers (such as fencing, vehicle barriers, towers, sensors, cameras, and other surveillance, communication, and detection equipment) and roads in the vicinity of the border of the United States. In order to ensure the expeditious construction of the barriers and roads that Congress prescribed in the IIRIRA in the area starting approximately 4.75 miles west of the Naco, Arizona Port of Entry to the western boundary of the SPRNCA and any and all land covered by the TRO, which is an area of high illegal entry into the United States, I have determined that it is necessary that I exercise the authority that was transferred to me by sections 1511 and 1517 of the HSA and that is vested in me by section 102(c) of the IIRIRA as amended by section 102 of the REAL ID Act. Accordingly, I hereby waive in their entirety, with respect to the construction of roads and fixed and mobile barriers (including, but not limited to, accessing the project area, the conduct of earthwork, excavation, fill, and site preparation, and installation and upkeep of fences, roads, supporting elements, drainage, erosion controls, safety features, surveillance, communication, and detection equipment of all types, radar and radio towers, and lighting) in the area starting approximately 4.75 miles west of the Naco, Arizona Port of Entry to the western boundary of the SPRNCA and any and all land covered by the TRO, all federal, state, or other laws, regulations and legal requirements of, deriving from, or related to the subject of, the following laws, as amended: The National Environmental Policy Act (Pub. L. 91–190, 83 Stat. 852 (Jan. 1, 1970) (42 U.S.C. 4321 *et seq.*)), the Endangered Species Act (Pub. L. 93–205, 87 Stat. 884 (Dec. 28, 1973) (16 U.S.C. 1531 *et seq.*)), the Federal Water Pollution Control Act (commonly referred to as the Clean Water Act) (Act of June 30, 1948, c. 758, 62 Stat. 1155 (33 U.S.C. 1251 *et seq.*)), the National Historic Preservation Act (Pub. L. 89–665, 80 Stat. 915 (Oct. 15, 1966) (16 U.S.C. 470 *et seq.*)), the Migratory Bird Treaty Act (16 U.S.C. 703 *et seq.*), the Clean Air Act (42 U.S.C. 7401 *et seq.*), the Archeological Resources Protection Act (Pub. L. 96–95, 16 U.S.C. 470aa *et seq.*), the Safe Drinking Water Act (42 U.S.C. 300f *et seq.*), the Noise Control Act (42 U.S.C. 4901 *et seq.*), the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (42 U.S.C. 6901 *et seq.*), the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9601 *et seq.*), the Federal Land Policy and Management Act (Pub. L. 94–579, 43 U.S.C. 1701 *et seq.*), the Fish and Wildlife Coordination Act (Pub. L. 73–121, 48 Stat. 401, 16 U.S.C. 661 *et seq.*), the Archaeological and Historic Preservation Act (Pub. L. 86–523, 16 U.S.C. 469 *et seq.*), the Antiquities Act (16 U.S.C. 431 *et seq.*), the Historic Sites, Buildings, and Antiquities Act (16 U.S.C. 461 *et seq.*), the Arizona-Idaho Conservation Act of 1988 (Pub. L. 100–696, 16 U.S.C. 460xx *et seq.*), the Wild and Scenic Rivers Act (Pub. L. 90–542, 16 U.S.C. 1281 *et seq.*), the Farmland Protection Policy Act (7 U.S.C. 4201 *et seq.*) and the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). I reserve the authority to make further waivers from time to time under the authority granted to me by section 102(c) of the IIRIRA, as amended by section 102 of the REAL ID Act, as I may determine to be necessary to accomplish the provisions of section 102 of IIRIRA.

Dated: October 19, 2007.

Michael Chertoff,

Secretary of Homeland Security.

[FR Doc. E7–21125 Filed 10–25–07; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket Nos. TSA–2006–24191; Coast Guard–2006–24196]

Transportation Worker Identification Credential (TWIC); Enrollment Date for the Port of Corpus Christi, Corpus Christi, TX

AGENCY: Transportation Security Administration; United States Coast Guard; DHS.

ACTION: Notice.

SUMMARY: The Department of Homeland Security (DHS) through the Transportation Security Administration (TSA) issues this notice of the dates for the beginning of the initial enrollment for the Transportation Worker Identification Credential (TWIC) for the Port of Corpus Christi, in Corpus Christi, TX.

DATES: TWIC enrollment in Corpus Christi, TX will begin on November 1, 2007.

ADDRESSES: You may view published documents and comments concerning the TWIC Final Rule, identified by the docket numbers of this notice, using any one of the following methods.

(1) Searching the Federal Docket Management System (FDMS) web page at *www.regulations.gov*;

(2) Accessing the Government Printing Office's Web page at *http://www.gpoaccess.gov/fr/index.html*; or

(3) Visiting TSA's Security Regulations Web page at *http://www.tsa.gov* and accessing the link for ''Research Center'' at the top of the page.

FOR FURTHER INFORMATION CONTACT: James Orgill, TSA–19, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202–4220. Transportation Threat Assessment and Credentialing (TTAC), TWIC Program, (571) 227–4545 e-mail: *credentialing@dhs.gov*.

Background

The Department of Homeland Security (DHS), through the United States Coast Guard and the Transportation Security Administration (TSA), issued a joint final rule (72 FR 3492; January 25, 2007) pursuant to the Maritime Transportation Security Act (MTSA), Pub. L. 107–295, 116 Stat. 2064 (November 25, 2002), and the Security and Accountability for Every Port Act of 2006 (SAFE Port Act), Pub. L. 109–347 (October 13, 2006). This rule requires all credentialed merchant mariners and individuals with unescorted access to secure areas of a regulated facility or vessel to obtain a TWIC. In this final rule, on page 3510, TSA and Coast Guard stated that a phased enrollment approach based upon risk assessment and cost/benefit would be used to implement the program nationwide, and that TSA would publish a notice in the **Federal Register** indicating when enrollment at a specific location will begin and when it is expected to terminate.

This notice provides the start date for TWIC initial enrollment at the Port of Corpus Christi, TX only. Enrollment in this port will begin on November 1, 2007. The Coast Guard will publish a separate notice in the **Federal Register** indicating when facilities within the Captain of the Port Zone Corpus Christi, including those in the Port of Corpus Christi, TX, must comply with the portions of the final rule requiring TWIC to be used as an access control measure. That notice will be published at least 90 days before compliance is required.

To obtain information on the pre-enrollment and enrollment process, and enrollment locations, visit TSA's TWIC Web site at *http://www.tsa.gov/twic*.

Issued in Arlington, Virginia, on October 23, 2007.

Stephen Sadler,

Director, Maritime and Surface Credentialing, Office of Transportation Threat Assessment and Credentialing, Transportation Security Administration.

[FR Doc. E7–21112 Filed 10–25–07; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2007–0089]

Notice of Meeting of The Departmental Advisory Committee on Commercial Operations of Customs and Border Protection and Related Homeland Security Functions (COAC)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security (DHS).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Departmental Advisory Committee on Commercial Operations of U.S. Customs and Border Protection and Related Homeland Security Functions (popularly known as ''COAC'') will meet on November 16, 2007 in Washington, DC. The meeting will be open to the public.

DATES: COAC will meet Friday, November 16th from 9 a.m. to 1 p.m. Please note that the meeting may close early if the committee has completed its business.

ADDRESSES: The meeting will be held at the Ronald Reagan Building in the Rotunda Ballroom, 1300 Pennsylvania Avenue, NW., Washington, DC 20004. Written material and comments should reach the contact person listed below by November 9th. Requests to have a copy of your material distributed to each member of the committee prior to the meeting should reach the contact person at the address below by November 9, 2007. Comments must be identified by USCBP–2007–0089 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: traderelations@dhs.gov.* Include the docket number in the subject line of the message.
- *Fax:* 202–344–2064.
- *Mail:* Ms. Wanda Tate, Office of International Affairs and Trade Relations, U.S. Customs and Border Protection, Department of Homeland Security, Room 8.5C, Washington, DC 20229.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the COAC, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Wanda Tate, Office of International Affairs and Trade Relations, U.S. Customs and Border Protection, Department of Homeland Security, 1300 Pennsylvania Ave., NW., Room 8.5C, Washington, DC 20229; *traderelations@dhs.gov;* telephone 202–344–1440; facsimile 202–344–2064.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (5 U.S.C., app.), DHS hereby announces the meeting of the Departmental Advisory Committee on Commercial Operations of U.S. Customs and Border Protection and Related Homeland Security Functions (COAC). COAC is tasked with providing advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within DHS or the Department of the Treasury.

The fourth meeting of the tenth term of COAC will be held at the date, time and location specified above. A tentative agenda for the meeting is set forth below.

Tentative Agenda

1. Post Incident Trade Resumption.
2. Secure Freight Initiative.
3. Advance Data Elements.
4. C–TPAT (Customs-Trade Partnership Against Terrorism).
5. ITDS (International Trade Data System).
6. ACE (Automated Commercial Environment).
7. Office of International Trade.
8. Import Safety Working Group.
9. Intellectual Property Rights.
10. World Customs Organization Updates.

Procedural

This meeting is open to the public. Please note that the meeting may close early if all business is finished.

Participation in COAC deliberations is limited to committee members, Department of Homeland Security officials, and persons invited to attend the meeting for special presentations.

All visitors to the Ronald Reagan building will have to go through a security checkpoint to be admitted to the building. Since seating is limited, all persons attending this meeting should provide notice, preferably by close of business Tuesday, November 13, 2007, to Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection, Department of Homeland Security, Washington, DC 20229, telephone 202–344–1440; facsimile 202–344–2064.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Wanda Tate as soon as possible.

Dated: October 23, 2007.

Michael C. Mullen,

Assistant Commissioner, Office of International Affairs and Trade Relations, U.S. Customs and Border Protection.

[FR Doc. E7–21121 Filed 10–25–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5125–N–43]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7262, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to John Hicks, Division of Property Management, Program Support Center, HHS, Room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: ARMY: Ms. Veronica Rines, Department of the Army, Office of the Assistant Chief of Staff for Installation Management, Attn: DAIM–ZS, Rm 8536, 2511 Jefferson Davis Hwy., Arlington, VA 22202; (703)

601–2545; GSA: Mr. John E.B. Smith, Deputy Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th and F Streets, NW., Washington, DC 20405; (202) 501–0084; INTERIOR: Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, 1849 C Street, NW., MS2603, Washington, DC 20240; (202) 513–0747; NAVY: Mr. Warren Meekins, Associate Director, Department of the Navy, Real Estate Services, Naval Facilities Engineering Command, Washington Navy Yard, 1322 Patterson Ave., SE., Suite 1000, Washington, DC 20374–5065; (202) 685–9305; (These are not toll-free numbers).

Dated: October 18, 2007.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

Title V, Federal Surplus Property Program

Suitable/Available Properties

Building

Massachusetts

Federal Office Bldg
Main & Bridge St.
Springfield, MA 01101
Landholding Agency: GSA
Property Number: 54200740002
Status: Excess
GSA Number: MA–6262–1
Comments: 30,000 sq. ft., 27% occupied, recommend complete system upgrade.

Montana

Sonstelie Hall USARC
1110 2nd St.
Kalispell, MT 59901–4202
Landholding Agency: GSA
Property Number: 54200740003
Status: Excess
GSA Number: 7–D–MT–0625
Comments: 14,635 sq. ft., most recent use—admin/classrooms/storage, subject to easements.

Suitable/Available Properties

Building

Samoa

Unit #25
Lima & FA Streets
Tafuna, AQ
Landholding Agency: GSA
Property Number: 54200740001
Status: Surplus
GSA Number: 9–U–AS–002AB
Comments: 1722 sq. ft., presence of lead paint, most recent use—residential, off-site use only or negotiate ground lease with local govt.

Land

Arizona

Portion Tract GR–11–20
Detention Basin
Phoenix, AZ 85050
Landholding Agency: Interior
Property Number: 61200740001
Status: Excess
Comments: 3.28 acres, road constructed
Summary for Suitable/Available Properties.
Total number of Properties = 4.

Unsuitable Properties

Building

Arizona

Bldgs. M5218, M5219, M5222
Papago Park Military Rsv.
Phoenix, AZ 85008
Landholding Agency: Army
Property Number: 21200740001
Status: Unutilized
Reasons: Within airport runway clear zone. Secured Area.Extensive deterioration.

4 Bldgs.
Papago Park Military Rsv.
M5234, M5238, M5242, M5247
Phoenix, AZ 85008
Landholding Agency: Army
Property Number: 21200740002
Status: Unutilized
Reasons: Within airport runway clear zone. Secured Area.Extensive deterioration.

Bldg. 1509
National Park
Grand Canyon, AZ 86023
Landholding Agency: Interior
Property Number: 61200740002
Status: Unutilized
Reasons: Extensive deterioration.

Unsuitable Properties

Building

California

Bldg. 800
National Park
Yosemite, CA 95389
Landholding Agency: Interior
Property Number: 61200740003
Status: Unutilized
Reasons: Extensive deterioration.

Bldgs. 124, 148
Naval Air Station
North Island, CA
Landholding Agency: Navy
Property Number: 77200740002
Status: Excess
Reasons: Secured Area.

Bldgs. 314, 341, 636
Naval Air Station
North Island, CA
Landholding Agency: Navy
Property Number: 77200740003
Status: Excess
Reasons: Secured Area.

Bldgs. 710, 802, 826
Naval Air Station
North Island, CA
Landholding Agency: Navy
Property Number: 77200740004
Status: Excess
Reasons: Secured Area.

Unsuitable Properties

Building

California

Bldgs. 60139, 60180
Naval Air Station
San Clemente, CA
Landholding Agency: Navy
Property Number: 77200740005
Status: Excess
Reasons: Secured Area.

Bldgs. 41313, 41314
Marine Corps Base
Camp Pendleton, CA 92055
Landholding Agency: Navy
Property Number: 77200740006
Status: Excess
Reasons: Secured Area. Extensive deterioration.

4 Bldgs.
Marine Corps Base, 41359, 41362, 41365, 41366
Camp Pendleton, CA 92055
Landholding Agency: Navy
Property Number: 77200740007
Status: Excess
Reasons: Secured Area. Extensive deterioration.

Unsuitable Properties

Building

California

Bldg. 43976
Marine Corps Base
Camp Pendleton, CA 92055
Landholding Agency: Navy
Property Number: 77200740008
Status: Excess
Reasons: Secured Area. Extensive deterioration.

Bldgs. 53440, 53831
Marine Corps Base
Camp Pendleton, CA 92055
Landholding Agency: Navy
Property Number: 77200740009
Status: Excess
Reasons: Secured Area. Extensive deterioration.

Bldg. 410365
Marine Corps Base
Camp Pendleton, CA 92055
Landholding Agency: Navy
Property Number: 77200740010
Status: Excess
Reasons: Secured Area. Extensive deterioration.

Unsuitable Properties

Building

Colorado

Bldgs. S6231, S6232
Fort Carson
El Paso, CO 80913
Landholding Agency: Army
Property Number: 21200740003
Status: Unutilized
Reasons: Secured Area.

Bldgs. S6234, S6250
Fort Carson
El Paso, CO 80913
Landholding Agency: Army
Property Number: 21200740004
Status: Unutilized
Reasons: Secured Area.

Georgia

Bldg. 8562
Fort Benning
Ft. Benning, GA 31905
Landholding Agency: Army
Property Number: 21200740005
Status: Unutilized
Reasons: Extensive deterioration.

Unsuitable Properties

Building

Georgia

4 Bldgs.
Fort Benning, 8668, 8684, 8685, 8764
Ft. Benning, GA 31905
Landholding Agency: Army
Property Number: 21200740006
Status: Unutilized
Reasons: Extensive deterioration.

Bldgs. 00956, 00958, 00966
Fort Stewart
Hinesville, GA 31314
Landholding Agency: Army
Property Number: 21200740007
Status: Excess
Reasons: Extensive deterioration.

Hawaii

Facilities 00001, 00002
Tanapag USARC
Tanapag, HI
Landholding Agency: Army
Property Number: 21200740008
Status: Unutilized
Reasons: Extensive deterioration.

Unsuitable Properties

Building

Hawaii

Bldg. 01284
Schofield Barracks
Wahiawa, HI 96786
Landholding Agency: Army
Property Number: 21200740009
Status: Unutilized
Reasons: Secured Area.

Bldgs. A2138, A2139
Schofield Barracks
Wahiawa, HI 96786
Landholding Agency: Army
Property Number: 21200740010
Status: Unutilized
Reasons: Secured Area.

Bldgs. 02137, E2138
Schofield Barracks
Wahiawa, HI 96786
Landholding Agency: Army
Property Number: 21200740011
Status: Unutilized
Reasons: Secured Area.

Bldgs. 02141, 02145
Schofield Barracks
Wahiawa, HI 96786
Landholding Agency: Army
Property Number: 21200740012
Status: Unutilized
Reasons: Secured Area.

Unsuitable Properties

Building

Kansas

Bldgs. 00111, 00417
Fort Leavenworth
Leavenworth, KS 66027
Landholding Agency: Army
Property Number: 21200740013
Status: Unutilized
Reasons: Extensive deterioration.

Kentucky

Bldgs. 01481, 06153, 06154
Fort Knox
Ft Knox, KY 40121
Landholding Agency: Army
Property Number: 21200740014
Status: Unutilized
Reasons: Extensive deterioration.

Maryland

Bldgs. E3850, E5699, E6882
Aberdeen Proving Ground
Harford, MD 21005
Landholding Agency: Army
Property Number: 21200740015
Status: Unutilized
Reasons: Secured Area.

Unsuitable Properties

Building

Maryland

4 Bldgs., Fort Meade, 2630, 4717, 4720, 4721
Anne Arundel, MD 20755
Landholding Agency: Army
Property Number: 21200740016.
Status: Unutilized.
Reasons: Secured Area.

Montana

4 Bldgs., Ft. Harrison, 0003A, T0003, T0024, T0562, Lewis & Clark, MT 59636.
Landholding Agency: Army
Property Number: 21200740018.
Status: Unutilized.
Reasons: Extensive deterioration.

New Jersey

5 Bldgs., Fort Dix, 02510, 02511, 2512, 2515, 9656, Burlington, NJ 08640.
Landholding Agency: Army
Property Number: 21200740019.
Status: Unutilized.
Reasons: Extensive deterioration.

Unsuitable Properties

Building

North Carolina

Bldg. P3839, Fort Bragg, Cumberland, NC 28310.
Landholding Agency: Army
Property Number: 21200740020
Status: Unutilized
Reasons: Extensive deterioration. Secured Area.

Bldgs. P6382, P6383, P6384
Fort Bragg
Cumberland, NC 28310
Landholding Agency: Army
Property Number: 21200740021
Status: Unutilized
Reasons: Extensive deterioration. Secured Area.

Bldgs. P6482, P6483, P6484
Fort Bragg
Cumberland, NC 28310
Landholding Agency: Army
Property Number: 21200740022
Status: Unutilized.
Reasons: Secured Area. Extensive deterioration.

Unsuitable Properties

Building

North Carolina

Bldg. 82105
Fort Bragg
Cumberland, NC 28310
Landholding Agency: Army
Property Number: 21200740023
Status: Unutilized
Reasons: Secured Area. Extensive deterioration.

Bldg. 247
Marine Corps Air Station
Cherry Point, NC
Landholding Agency: Navy
Property Number: 77200740001
Status: Unutilized
Reasons: Extensive deterioration. Secured Area.

Oklahoma

Bldgs. 0008A, 0008B
McAlester AAP
Pittsburg, OK 74501
Landholding Agency: Army
Property Number: 21200740024
Status: Excess
Reasons: Secured Area. Within 2000 ft. of flammable or explosive material.

Unsuitable Properties

Building

Oklahoma

4 Bldgs.
McAlester AAP, 00137, 00484, 00674, 00717
Pittsburg, OK 74501
Landholding Agency: Army
Property Number: 21200740025
Status: Excess
Reasons: Secured Area. Within 2000 ft. of flammable or explosive material.

Pennsylvania

Bldg. 00301
Carlisle Barracks
Cumberland, PA 17013
Landholding Agency: Army
Property Number: 21200740026
Status: Unutilized
Reasons: Extensive deterioration.

Puerto Rico

Sectors #42, #44
Natl Historic Site
San Miguel, PR
Landholding Agency: Interior
Property Number: 61200740004
Status: Unutilized
Reasons: Extensive deterioration.

Unsuitable Properties

Building

Tennessee

Bldg. F0013
Milan AAP
Gibson, TN 38358
Landholding Agency: Army
Property Number: 21200740027
Status: Excess
Reasons: Within 2000 ft. of flammable or explosive material. Secured Area. Extensive deterioration.

Bldgs. W0055, W0058
Milan AAP
Gibson, TN 38358
Landholding Agency: Army
Property Number: 21200740028
Status: Excess
Reasons: Extensive deterioration. Within 2000 ft. of flammable or explosive material. Secured Area.

Bldg. F0100
Milan AAP
Gibson, TN 38358
Landholding Agency: Army
Property Number: 21200740029
Status: Excess
Reasons: Within 2000 ft. of flammable or explosive material. Secured Area. Extensive deterioration.

Unsuitable Properties

Building

Texas

Bldg. 1235
Fort Bliss
El Paso, TX 79916
Landholding Agency: Army
Property Number: 21200740030
Status: Unutilized
Reasons: Secured Area. Extensive deterioration.

Virginia

Bldgs. US042, US044, US45B
Radford AAP
Montgomery, VA 24013
Landholding Agency: Army
Property Number: 21200740031
Status: Underutilized
Reasons: Within 2000 ft. of flammable or explosive material. Secured Area.

Bldg. 01001
Radford AAP
Montgomery, VA 24013
Landholding Agency: Army
Property Number: 21200740032
Status: Underutilized
Reasons: Within 2000 ft. of flammable or explosive material. Secured Area.

Unsuitable Properties

Building

Virginia

Bldgs. 1332, 1529
Fort Lee
Prince George, VA 23801
Landholding Agency: Army
Property Number: 21200740033
Status: Unutilized
Reasons: Extensive deterioration.

5 Bldgs.
Fort Lee
07103, 07104, 07107, 07108, 07109
Prince George, VA 23801
Landholding Agency: Army
Property Number: 21200740034
Status: Unutilized
Reasons: Extensive deterioration.

6 Bldgs.
Fort Lee
Prince George, VA 23801
Landholding Agency: Army
Property Number: 21200740035
Status: Unutilized
Directions: 07110, 07112, 07114, 07121, 07122, 07126
Reasons: Extensive deterioration.

Unsuitable Properties

Building

Virginia

6 Bldgs.
Defense Supply Center
Richmond, VA 23297
Landholding Agency: Army
Property Number: 21200740036
Status: Unutilized
Directions: 00170, 00171, 00172, 00173, 00174, 00175
Reasons: Secured Area.

Bldgs. 00429, 01728, 01734
Fort Eustis
Ft. Eustis VA 23604
Landholding Agency: Army
Property Number: 21200740037
Status: Unutilized
Reasons: Extensive deterioration.

Washington

Bldgs. 62, 63
Yakima, WA 98944
Landholding Agency: Interior
Property Number: 61200740005
Status: Unutilized
Reasons: Extensive deterioration.

Unsuitable Properties

Building

Washington

5 Bldgs., 74, 75, 77, 78, 79
Yakima, WA 98944
Landholding Agency: Interior
Property Number: 61200740006
Status: Unutilized
Reasons: Extensive deterioration.

Wisconsin

Bldgs. R031I. R031S
Fort McCoy, Monroe WI 54656
Landholding Agency: Army
Property Number: 21200740038
Status: Unutilized
Reasons: Extensive deterioration.

Bldgs. 01092, 01093, 01094
Fort McCoy
Monroe, WI 54656
Landholding Agency: Army
Property Number: 21200740039
Status: Unutilized
Reasons: Extensive deterioration.

Unsuitable Properties

Land

Maryland

Approx. 1 Acre
Fort Meade
Anne Arundel, MD 20755
Landholding Agency: Army
Property Number: 21200740017
Status: Unutilized
Reasons: Other—no public access.

Summary for Unsuitable Properties

Total number of Properties = 133

Summary of All Properties

Suitable/Available Properties = 4
Suitable/Unavailable Properties = 0
Suitable/To Be Excessed = 0
* * Suitable/Undefined * * = 0
Total Suitable = 4
Total Unsuitable = 133
Total number of Properties = 137
Properties Resubmitted = 0

[FR Doc. E7–20858 Filed 10–25–07; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

U.S. Geological Survey

Agency Information Collection Activities: Submitted for Office of Management and Budget (OMB) Review; Comment Request

AGENCY: U.S. Geological Survey (USGS), Interior.

ACTION: Notice of an extension of an information collection (1028–0056).

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), we are notifying the pubic that we have submitted to OMB an information collection request (ICR) to renew approval of the paperwork requirements for ''North American Reporting Center for Amphibian Malformations (NARCAM) Voluntary Observation Submission Form.'' This notice also provides the public a second opportunity to comment on the paperwork burden of this form. The form is available online at *http://frogweb.nbii.gov/narcam/report.html.*

DATES: Submit written comments by November 26, 2007.

ADDRESSES: Please submit comments on this information collection directly to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs, Attention: Desk Office for the Department of the Interior via OMB e-mail: (*OIRA_DOCKET@omb.eop.gov);* or by fax (202) 395–6566; and identify your submission with #1028–0a56.

Please also submit a copy of your comments to the Department of the Interior, USGS, via:

- *E-mail: atravnic@usgs.gov.* Use Information Collection Number 1028–0056 in the subject line.
- *Fax:* (703) 648–7069. Use Information Collection Number 1028–0056 in the subject line.
- Mail or hand-carry comments to the Department of the Interior; USGS Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192. Please reference Information Collection 1028–0056 in your comments.

FOR FURTHER INFORMATION CONTACT: Lisa Zolly at (703) 648–4277. Copies of the full Information Collection Request and the forms can be obtained at no cost at *http://www.reginfo.gov* or by contacting the USGS clearance officer at the phone number listed below.

SUPPLEMENTARY INFORMATION:

Title: North American Reporting Center for Amphibian Malformations (NARCAM) Voluntary Observation Reporting Form.

OMB Control Number: 1028–0056.

Form Number: Web-based collection form; no form number.

Abstract: Respondents to this form voluntarily supply the U.S. Geological Survey, National Biological Information Infrastructure Program with data and information regarding observations of malformed amphibians. Once the information is peer-reviewed by a professional herpetologist, this information will be published online in the North American Reporting Center for Amphibian Malformations database for use by Government agencies, natural resources managers, researchers, education programs, and the general public.

We will protect information considered proprietary under the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2), and under regulations at 30 CFR 250.197, ''Data and information to be made available to the public or for limited inspection.'' Responses are voluntary. No questions of a ''sensitive'' nature are asked. We intend to release data collected on the NARCAM online form only in a format that is not reporter-specific; no information that would identify an individual reporter will be released to the public.

Frequency: Voluntary submissions. Most reporters submit one-time observational reports; however, a small percentage submits multiple reports as malformations are observed.

Estimated Number and Description of Respondents: Approximately 150 public citizens, natural resources managers, land managers, and biologists annually.

Estimated Number of Responses: Historical average of 300 annually; many respondents, particularly researchers and resource managers, submit more than one response annually.

Annual burden hours: 150.

Estimated Annual Reporting and Recordkeeping ''Hour'' Burden: The currently approved ''hour'' burden is 150 hours. We estimate the public reporting burden averages 30 minutes per response. This includes the time for reviewing instructions, gathering and maintaining data, and completing and reviewing the information.

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden: We have not identified any ''non-hour cost'' burdens associated with this collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct a sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) (44 U.S.C. 3501, *et seq.*) requires each agency ''* * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *'' Agencies must specifically solicit comments to: (a) Evaluate whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) evaluate the accuracy of the agency's estimated of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

To comply with the public consultation process, on August 22, 2007, we published a **Federal Register** notice (72 FR pp. 47065–47066) announcing that we would submit this ICR to OMB for approval. The notice provided the required 60-day public comment period. We have received no comments in response to the notice.

USGS Information Collection Clearance Officer: Alfred Travnicek, 703–648–7231.

Dated: October 22, 2007.

Gladys A. Cotter,

Associated Chief Biologist for Information, U.S. Geological Survey.

[FR Doc. 07–5300 Filed 10–25–07; 8:45 am]

BILLING CODE 4311–AM–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–958–6310–PF–24 1A]

Submission to Office of Management and Budget—Information Collection, OMB Control Number 1004–0168

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) has submitted a request for an extension of an approved information collection to the Office of Management and Budget (OMB) for approval.

DATES: The OMB is required to respond to this request within 60 days but may respond after 30 days. Submit your comments to OMB at the address below by November 26, 2007 to receive maximum consideration.

ADDRESSES: Send comments to the OMB, Interior Department Desk Officer (1004–0168), at OMB–OIRA via e-mail *OIRA_DOCKET@omb.eop.gov* or via facsimile at (202) 395–6566. Also please send a copy of your comments to BLM via Internet and include your name, address, and ATTN: 1004–0168 in your Internet message to *comments_washington@blm.gov* or via mail to: U.S. Department of the Interior, Bureau of Land Management, Mail Stop 401LS, 1849 C Street, NW., ATTN: Bureau Information Collection Clearance Officer (WO–630), Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: You may contact Ted Hudson to obtain copies and explanatory material on this information collection at (202) 452–5042. Persons who use a telecommunication device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) on 1–800–877–8330, 24 hours a day, seven days a week, to contact Mr. Hudson.

SUPPLEMENTARY INFORMATION: On June 9, 2006, the BLM published a notice in the **Federal Register** (71 FR 33481) requesting comments on the information collection. The comment period closed on August 8, 2006. The BLM did not receive any comments.

We are soliciting comments on the following:

(a) Whether the collection of information is necessary for the proper functioning of the agency, including whether the information will have practical utility;

(b) The accuracy of our estimates of the information collection burden, including the validity of the methodology and assumptions we use;

(c) Ways to enhance the quality, utility, and clarity of the information collected; and

(d) Ways to minimize the information collection burden on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Tramroads and Logging Roads (43 CFR part 2810).

OMB Control Number: 1004–0168.

Abstract: The BLM provides for tramroads and logging roads over the Revested Oregon and California Railroad and Reconveyed Coos Bay Wagon Road Grant Lands (O. and C. lands) 43 CFR part 2810, subpart 2812. These regulations implement the following statutes:

(1) Act of August 28, 1937 (43 U.S.C. 1181a & b); and

(2) The Federal Land Policy and Management Act of 1976 (43 U.S.C. 1762).

The BLM uses this information to approve use of BLM roads for access to timber on the O. and C. lands, and to determine the amount of charges for such use.

Burden Estimate Per Form: We estimate the completion time for the form information that is submitted quarterly by the private sector as follows:

Burden hours information collected	Number of actions per year	Burden hours per action	Total annual burden hours
(a) Report of Road Use (2812–6) and related non-form information in 43 CFR part 2810	272	8	2,176
Totals	272		2,176

Annual Responses: 272.
Application Fee Per Response: 0.
Annual Burden Hours: 2,176.

Dated: October 22, 2007.

Ted R. Hudson,

Acting Chief, Division of Regulatory Affairs.

[FR Doc. E7–21079 Filed 10–25–07; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–800–1610–DP 016C]

Notice of Availability of the Canyons of the Ancients Draft Resource Management Plan and Draft Environmental Impact Statement, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA, 42 U.S.C. 4321 *et seq.*) and the Federal Land Policy and Management Act (FLPMA) of 1976 (FLPMA, 43 U.S.C. 1701 *et seq.*), the Bureau of Land Management (BLM) has prepared a Draft Resource Management Plan/Draft Environmental Impact Statement (DRMP/DEIS) for the Canyons of the Ancients National Monument and by this notice is announcing the opening of the comment period. This notice also meets BLM requirements in 43 CFR 1610.7–2(b) concerning potential Areas of Critical Environmental Concern (ACECs).

DATES: A 90-day public comment period will begin the date the Environmental Protection Agency publishes their Notice of Availability in the **Federal Register**. The Canyon of the Ancients National Monument will announce future meetings or hearings and any other public involvement activities at least 15 days in advance through public notices, local media news releases, and/or mailings, and posting on the project Web site at *http://www.blm.gov/rmp/canm*. Public meetings will be held in Cortez, Denver, and Durango, Colorado and in other locations, if warranted.

ADDRESSES: The DRMP/DEIS will be posted on the Internet at: *http://www.blm.gov/rmp/canm/*. You may submit comments by any of the following methods:

Web site: *http://www.blm.gov/rmp/canm/*.

Fax: (970) 882–7035.

Mail: Monument Manager, Canyons of the Ancients National Monument, 27501 Highway 184, Dolores, CO 81323.

Comments, including names and addresses of respondents, will be available for public review at the Anasazi Heritage Center, 27501 Hwy 184, Dolores, CO 81323. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so. Copies of the DRMP/DEIS are also available during regular business hours at the following locations:

Anasazi Heritage Center, 27501 Highway 184, Dolores, CO 81323.
Dolores Public Lands Center, 29211 Highway 184, Dolores, CO 81323.
San Juan Public Lands Center, 15 Burnett Court, Durango, CO 81301.
Dolores Public Library, 420 Railroad Ave., Dolores, CO 81323.
Cortez Public Library, 202 N. Park, Cortez, CO 81321.
Mancos Public Library, 111 N. Main, Macos, CO 81328.
Durango Public Library, 1188 E. 2nd Ave, Durango, CO 81301.

FOR FURTHER INFORMATION CONTACT: Heather Musclow, Monument Planner, Canyons of the Ancients National Monument, 27501 Highway 184, Dolores, CO 81323; Phone: (970) 882–5632.

To have your name added to the Canyons of the Ancients Resource Management Plan mailing list or to view and download the DRMP/DEIS in portable document format (PDF) go to the project Web site: *http://www.blm.gov/rmp/canm/*.

SUPPLEMENTARY INFORMATION: The planning area is located in Southwest Colorado in Dolores and Montezuma counties. The plan will provide a framework to guide subsequent management decisions on approximately 164,000 acres managed by the BLM. Within the Monument boundary, there are approximately 400 acres of National Park Service lands (Hovenweep National Monument) and 18,000 acres of private inholdings. The Canyons of the Ancients National Monument is currently being managing under the BLM 1985 San Juan/San Miguel RMP and the Interim Guidance provided after the Monument was established.

- San Juan/San Miguel Resource Management Plan.

The current RMP was approved in 1985 and has been amended five times. The Wilderness Study Areas (WSA) within the Monument are being managed under interim guidance provided by the Interim Management Policy and Guidance for Lands under Wilderness Review until such time that Congress makes a final wilderness decision. The DRMP/DEIS discusses how those lands would be managed if Congress released them from wilderness study.

The Canyons of the Ancients National Monument has worked extensively with the community, interested and affected publics, Native American tribes, and cooperating agencies in the development of the DRMP/DEIS. The Monument has conducted a broad community-based public input process. Cooperating agencies include The Colorado State Historical Society and the United States Fish and Wildlife Service. Five alternatives are analyzed in the DRMP/DEIS.

- *Alternative I:* This is the No Action Alternative. This alternative is comprised of current management actions and goals and assumes existing or approved land uses would continue.

Current management actions are assembled from three sources: Colorado Interim Management for Canyons of the Ancients National Monument (BLM 2001f), Anasazi ACEC Plan Management Guideline (BLM 1986a), and San Juan/San Miguel RMP (BLM 1985). Under this alternative, cultural resource sites would continue to be developed for visiting and interpretation.

• *Alternative II:* This alternative maximizes cultural resource protection by avoiding impacts to cultural resource communities, sites and isolated finds. This management strategy maintains large blocks of undisturbed land that provide information on not only individual sites and artifacts but also their interconnectedness (i.e., how they relate to each other). Alternative II would develop the ''outdoor museum'' concept for self-discovery of cultural and natural resources. The outdoor museum concept provides a backcountry experience to visiting publics. In addition, 13 cultural sites would be developed for public access, facilitating visitation through developed routes and interpretive signs. The development of these cultural resource sites would enhance front country visitor experiences.

• *Alternative III:* This alternative emphasizes the protection of cultural resource communities and sites, while providing for resource use and development. This management strategy also maintains large blocks of undisturbed land, although not as large as Alternative II, and provides for the retrieval of information on not only individual sites but also their interconnectedness (i.e., how they relate to each other). Alternative III would develop the ''outdoor museum'' concept for self-discovery of cultural and natural resources in addition to developing 13–25 sites for public access.

• *Alternative IV:* This alternative emphasizes the protection of cultural resource communities and sites while encouraging resource use and development. This management strategy maintains large blocks of undisturbed land, although not as large as Alternative II, and provides for the retrieval of information on not only individual sites but also their interconnectedness (i.e., how they relate to each other). Alternative IV would develop the ''outdoor museum'' concept for self-discovery of cultural and natural resources in addition to developing 13–25 sites for public access.

• *Alternative V:* This is the Preferred Alternative. Alternative V represents the best fit between protection of objects of the Monument and the multiple use of all resources. Alternative V emphasizes the protection of cultural resource communities and sites, while providing for resource use and development. This management strategy maintains large blocks of undisturbed land, although not as large as Alternative II, and provides for the retrieval of information on not only individual sites and artifacts but also their interconnectedness (i.e., how they relate to each other). Alternative V would promote self-discovery through the ''outdoor museum'' concept, in addition to 13–25 cultural sites developed for public access.

Section 202(c)(3) of FLPMA requires the DRMP/DEIS to examine the designation of Areas of Critical Environmental Concern (ACEC) on BLM lands. The Monument was an Anasazi ACEC prior to being designated a Monument. The ACEC designation has continued but is considered of little value since the Monument designation provides protection of the same outstanding characteristics. Therefore, the Anasazi ACEC designation is proposed to be dropped in this plan. The Values and Limitations to protect the natural and cultural resources of the Monument are consistent with the previous ACEC. The McElmo Research Natural Area (RNA) would continue its ACEC designation with four units proposed located immediately north of, and adjacent to, McElmo Canyon:

• McElmo Unit (existing RNA, 427 acres),

• McElmo Expansion Unit (2,738 acres),

• Cannonball Mesa Unit (2,797 acres), and

• Sand Canyon Unit (1,864 acres).

All of the RNA units have the same values and use limitations.

Potential ACEC acres vary by alternative as shown in the table below.

ACRES OF BLM-MANAGED SURFACE ESTATE PROPOSED TO BE MANAGED AS ACECS UNDER THE ALTERNATIVES IN THE DRAFT LMP/EIS

Values and use limitations	Alternative I (no action)	Alternative II	Alternative III	Alternative IV	Alternative V (preferred)
McElmo RNA (ACEC) ..... *Values:* natural systems (sensitive plants) *Limitations:* apply a no surface occupancy (NSO/NGD) stipulation for areas not previously leased for oil and gas leasing and other surface disturbing activities.	427	7,826	427	7,297	7,826
Manage as VRM I. Total Acres	427	7,826	427	427	7,826

Major issues considered in the DRMP/DEIS include:

• *Cultural Issues:* Concerns included the protection/preservation of cultural resources for purposes of current and future scientific research, education, and Native American cultural heritage; development opportunities; access to cultural resource sites; and looting.

• *General Recreation:* Concerns included permitted and restricted types of recreation and their allocated ''zones'' or locations, and related roads and transportation issues, such as motorized and mechanized access and limitations.

• *Transportation Network:* Concerns included road closures and access, and road maintenance and improvements.

• *Rangeland Management/Grazing:* Concerns included management for Land Health Standards, administration of grazing allotments, and evaluation of grazing impacts in terms of current standards and guidelines.

• *Mineral Resources:* Concerns included limitations on oil and gas exploration and development, mitigation of impacts from existing and new mineral exploration and development.

• *Visitor Use:* Concerns included visitor education opportunities, facility development and improvements, and commercial and not-for-profit tours.

• *Soil, Water, and Air:* Concerns included the protection/preservation of soil, water, and air quality.

Sally Wisely,

Colorado State Director.

[FR Doc. E7–21011 Filed 10–25–07; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT050–1610–012J]

Notice of Availability of the Draft Resource Management Plan (DRMP) and Draft Environmental Impact Statement (DEIS) for the Richfield Field Office in Garfield, Piute, Sanpete, Sevier, and Wayne Counties, UT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA, 42 U.S.C. 4321 *et seq.*) and the Federal Land Policy and Management Act of 1976 (FLPMA, 43 U.S.C. 1701 *et seq.*), the Bureau of Land Management (BLM) hereby gives notice that the Richfield Draft Resource Management Plan and Draft Environmental Impact Statement (DRMP/DEIS) is available for a 90-day public review and comment period. This notice also meets requirements in part 1610, 7–2(b) concerning potential Areas of Critical Environmental Concern (ACECs).

DATES: To ensure that they will be considered, BLM must receive written comments on the DRMP/DEIS within 90 days following the date the Environmental Protection Agency publishes its notice of availability in the **Federal Register**. The BLM will announce public meetings and other public-involvement activities at least 15 days in advance through public notices, news releases, direct mailings, and on the project Web site at: *http://www.blm.gov/rmp/ut/richfield/*. Public meetings will be held in Junction, Loa, Manti, Richfield, and Salt Lake City, and in other locations if warranted.

ADDRESSES: Address written comments to: RMP Comments, Richfield Field Office, Bureau of Land Management (BLM), 150 East 900 North, Richfield, Utah 84701. Comments may also be faxed to the Field Office at 435–896–1550, or submitted electronically by e-mail: *UT_Richfield_Comments@blm.gov*. Comments and information submitted on the Supplement to the Vernal Field Office DRMP/DEIS, including names, e-mail addresses, and street addresses of respondents, will be available for public review and disclosure at the Vernal Field Office address listed below. The BLM will not accept anonymous comments. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

FOR FURTHER INFORMATION CONTACT: For further information, or to have your name added to the Richfield RMP mailing list, visit the RMP Web site: *http://www.blm.gov/rmp/ut/richfield/*. Or, you may contact Cornell Christensen, RMP Project Manager, Richfield BLM Field Office, 150 East 900 North, Richfield, Utah 84701, phone 435–896–1532. The DRMP/DEIS can be viewed and downloaded in portable document format (PDF) at the project Web site: *http://www.blm.gov/rmp/ut/richfield/*. Copies of the DRMP/DEIS are also available at the Bureau of Land Management (BLM) Richfield Field Office.

SUPPLEMENTARY INFORMATION: The DRMP/DEIS addresses public lands and resources managed by the Richfield Field Office in Garfield, Piute, Sanpete, Sevier, and Wayne Counties, Utah. These lands and resources are currently managed under six old land use plans: Cedar-Beaver-Garfield-Antimony RMP (1986), Forest Management Framework Plan (MFP) (1982), Henry Mountains MFP (1982), Mountain Valley MFP (1981), Parker Mountain MFP (1983), and San Rafael RMP (1991). The planning area includes approximately 2.1 million acres of BLM-administered surface lands and additional Federally-owned minerals under Federal, state, and private lands in the area. Decisions in the Richfield RMP will only apply to BLM-administered public lands and Federally-owned minerals. The DRMP/DEIS proposes and analyzes five alternatives for future management of the public lands and resources in the planning area. Alternative B is BLM's proposed action and the preferred alternative. Major issues considered in the DRMP/DEIS include oil and gas leasing, mining, range and livestock management, access and transportation, recreation and off-highway vehicle management, special status species, special designations (including Areas of Critical Environmental Concern [ACECs] and wild and scenic rivers), and lands with wilderness characteristics, among others. When completed, the new RMP will replace management decisions in the existing land use plans. As required by law, the DRMP/DEIS considers the designation and protection of ACECs. ACEC values and resource use limitations vary by ACEC, and the ACECs themselves vary by alternative. See table below.

ACRES OF PUBLIC LAND TO BE MANAGED AS ACECS UNDER THE ALTERNATIVES IN THE RICHFIELD DRMP/DEIS

Values and use limitations	Alt. N (no action)	Alt. A	Alt. B (preferred)	Alts. C and D
Badlands ACEC Values: Outstanding scenery, special status species, natural processes (wind erosion), riparian areas, relict vegetation. Limitations: Designate scenic areas outside Wilderness study Areas (WSAs) as Visual Resource Management (VRM) II, limit or close to Off-Highway Vehicle (OHV) use, close to oil and gas leasing, propose withdrawal from mineral entry.	0	0	0	88,900.
Beaver Wash ACEC Values: Desert riparian community. Limitations: Close to OHV use, close to oil and gas leasing, close to livestock grazing, propose withdrawal from mineral entry.	3,400	0	0	(Included in Dirty Devil/North Wash ACEC).
Bull Creek ACEC Value: Cultural resources. Limitations: Limit off-highway vehicles to designated routes.	0	0	0	4,800.

ACRES OF PUBLIC LAND TO BE MANAGED AS ACECS UNDER THE ALTERNATIVES IN THE RICHFIELD DRMP/DEIS—Continued

Values and use limitations	Alt. N (no action)	Alt. A	Alt. B (preferred)	Alts. C and D
Dirty Devil/North Wash ACEC: Values: Outstanding scenery, cultural resources, paleontological resources, wildlife, special status species, relict vegetation, riparian areas. Limitations: Designate scenic areas outside WSAs as VRM II, close to oil and gas leasing or lease with no surface occupancy and propose withdrawal from mineral entry. Permit no domestic sheep grazing. Close to OHV use or limit to designated routes.	0	0	0	205,300.
Fremont Gorge/Cockscomb Values ACEC: Cultural resources, outstanding scenery, riparian areas, special status plant species, wildlife. Limitations: Designate scenic areas outside WSAs as VRM II, open to oil and gas leasing with no surface occupancy and propose withdrawal from mineral entry. Close to OHV or limit to designated routes.	0	0	0	34,300.
Gilbert Badlands ACEC Values: Badlands geology. Limitations: Close to OHV use, designate open to oil and gas leasing with no surface occupancy, and propose withdrawal from mineral entry.	3,700	0	0	(Included in Badlands ACEC).
Henry Mountains ACEC Values: Outstanding scenery, cultural resources, wildlife, special status species, ecological values, riparian areas. Limitations: Designate scenic areas outside WSAs as VRM II, close to off-highway vehicles or limit to designated routes, close to oil and gas leasing, and propose withdrawal from mineral entry.	0	0	0	288,200.
Horseshoe Canyon ACEC Values: Outstanding scenery, cultural resources, special status species, riparian areas. Limitations: Designate scenic areas outside WSAs as VRM II, open to oil and gas leasing with no surface occupancy, and propose withdrawal from mineral entry.	0	0	0	40,900.
Kingston Canyon ACEC Values: Wildlife habitat and riparian areas. Limitations: Limit off-highway vehicles to designated routes and suppress unwanted fires.	0	0	0	22,100.
Little Rockies ACEC Values: Outstanding scenery, wildlife, special status species, riparian areas. Limitations: Designate scenic areas outside WSAs as VRM II, open to oil and gas leasing with no surface occupancy and propose withdrawal from mineral entry. Change class of livestock from sheep to cattle.	0	0	0	49,200.
Lower Muddy Creek ACEC Values: Outstanding scenery, special status plants, riparian areas. Limitations: Designate scenic areas as VRM Class II and close to oil and gas leasing.	0	0	0	16,200.
No Man Mesa ACEC Value: Relict vegetation. Limitations: Close to OHV use, close to oil and gas leasing, and propose withdrawal from mineral entry.	0	0	0	(Included in Henry Mountains ACEC).
North Caineville Mesa ACEC Value: Relict vegetation. Limitations: Close to OHV use, open to oil and gas leasing with no surface occupancy, close to livestock grazing, identify as unsuitable for coal leasing, and propose withdrawal from mineral entry.	3,800	0	3,800	(Included in Badlands ACEC).
Old Woman Front ACEC Value: Relict vegetation. Limitations: Close to livestock grazing, close to OHV use, close to oil and gas leasing and propose withdrawal from mineral entry.	0	0	330	330.
Parker Mountain ACEC Value: Sagebrush-steppe habitat, special status species. Limitations: Limit off-highway vehicles to designated routes, suppress unwanted wildfires, and implement proper grazing practices.	0	0	0	107,900.
Quitchupah Creek ACEC Values: Cultural resources, Native American values, riparian areas. Limitations: Limit off-highway vehicles to designated routes.	0	0	0	180.
Rainbow Hills ACEC Values: Wildlife habitat and special status plants. Limitations: Suppress unwanted wildfires, close to OHV use, and open to oil and gas leasing with no surface occupancy.	0	0	0	4,000.

ACRES OF PUBLIC LAND TO BE MANAGED AS ACECS UNDER THE ALTERNATIVES IN THE RICHFIELD DRMP/DEIS—Continued

Values and use limitations	Alt. N (no action)	Alt. A	Alt. B (preferred)	Alts. C and D
Sevier Canyon ACEC Values: Wildlife habitat, special status species, riparian areas. Limitations: Suppress unwanted wildfires, limit off-highway vehicles to designated routes and close routes seasonally.	0	0	0	8,900.
South Caineville Mesa ACEC Value: Relict vegetation. Limitations: Close to OHV use, open to oil and gas leasing with no surface occupancy, close to livestock grazing, propose withdrawal from mineral entry.	5,300	0	0	(Included in Badlands ACEC).
Special Status Species ACEC Values: Special Status Species and habitat. Limitations: Close or limit OHV use to designated routes and open to oil and gas leasing with controlled surface use stipulations.	0	0	0	15,100.
Thousand Lake Bench ACEC Values: Cultural resources, special status plants and riparian areas. Limitations: Close to off-highway vehicles or limit to designated routes.	0	0	0	500.
Total	16,200	0	4,130	886,810.

The application of the Federal coal unsuitability criteria to the Henry Mountains and Emery Coal Fields is included in Appendix 8 of the DRMP/DEIS. As required by 43 CFR 3461.2–1(a)(2), the public is invited to comment on the results of the application of the criteria and the application process used. The criteria are listed under 43 CFR 3461.5. Additionally, the BLM will conduct a public hearing on coal leasing potential in the DRMP/DEIS before it is finalized, if such a hearing is requested by any person who may be adversely affected by adoption of the proposed plan.

Selma Sierra,

Utah State Director.

[FR Doc. 07–5283 Filed 10–25–07; 8:45 am]

BILLING CODE 4310–DK–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID 320 7122 EO 7979]

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Availability of Final Environmental Impact Statement (FEIS) for the Smoky Canyon Mine, Panels F and G

AGENCIES: DOI Bureau of Land Management (BLM), Lead Agency; USDA Forest Service (FS), Co-lead Agency; and the State of Idaho, Idaho Department of Environmental Quality, Cooperating Agency.

ACTION: Notice of Availability of the Final Environmental Impact Statement for the Smoky Canyon Mine, Panels F and G Mine Expansion Project.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA, 42 U.S.C. 4321 *et. seq.*) and the Federal Land Policy and Management Act of 1976 (FLPMA, 43 U.S.C. 1701 *et. seq.*), the DOI Bureau of Land Management (Lead Agency) and the USDA Forest Service (Co-lead Agency) announce the availability of the FEIS for the Smoky Canyon Mine, Panels F and G Mine Expansion Project.

DATES: The FEIS is now available for public review. The BLM Record of Decision will be released no sooner than 30 days after publication of a Notice of Availability of the FEIS in the **Federal Register** by the Environmental Protection Agency.

ADDRESSES: Copies of the FEIS have been sent to affected Federal, State, and local Government agencies and to interested parties. The FEIS will be available in limited quantities at the Bureau of Land Management, Pocatello Field Office, 4350 Cliffs Drive, Pocatello, Idaho 83204, phone (208) 478–6340 and the Caribou-Targhee National Forest, Soda Springs Ranger District, 410 E. Hooper Avenue, Soda Springs, Idaho 83276, phone (208) 547–4356. It will also be available on the BLM Web site at: *http://www.blm.gov/id/st/en/fo/pocatello/programs/planning/smoky_canyon_mine.html* and the Caribou-Targhee National Forest Web site at: *http://www.fs.fed.us/r4/caribou-targhee/phosphate.*

FOR FURTHER INFORMATION CONTACT: Bill Stout, Bureau of Land Management, phone (208) 478–6340; or Jeff Jones, Caribou-Targhee National Forest, phone (208) 236–7572.

SUPPLEMENTARY INFORMATION: The FEIS was prepared to provide decision makers and the public with a complete and objective evaluation of significant environmental impacts, beneficial and adverse, resulting from the proposed action and from all reasonable alternatives.

The proposed extension of on-going mining operations, into Panels F and G, lies within the Caribou-Targhee National Forest in Southeast Idaho, on lands administered by the FS associated with two Federal phosphate leases held by the J.R. Simplot Company (the lessee, hereinafter referred to as the proponent) and are administered by the BLM under authority of the Mineral Leasing Act of 1920. Mining, to recover phosphate ore, and reclamation would take place over an estimated 16-year period. The environmental impacts of the proponent's Proposed Action, six mining alternatives, one no-mining alternative, and eight transportation alternatives are analyzed in the FEIS.

The BLM Idaho State Director, or delegated official, will consult with the Caribou-Targhee National Forest Supervisor regarding surface management and mitigation on leased lands within the Caribou-Targhee National Forest and will make a decision regarding approval of the proposed Mine & Reclamation Plan and several proposed lease modifications. The FS will also make a decision whether to authorize off-lease facilities such as roads and power lines.

The proposed Mine & Reclamation Plan was submitted by the proponent in April 2003. The plan consists of the development of two open mine pits (Panel F, to be located on Federal Phosphate Lease I–27512, and Panel G,

to be located on Federal Phosphate Lease I–01441); extension of a power line from the existing Smoky Canyon facilities; construction of permanent external overburden storage areas and runoff/sediment control facilities; and construction of an electrical substation and other mine support facilities. A 2.5-mile haul/access road is proposed to transport ore from Panel F to the existing mill at the Smoky Canyon Mine. Once Panel F is mined out, an additional 7.8-mile haul road is proposed to be constructed from Panel G to the existing Panel F, to transport ore to the mill.

The proposed Panel F pit would extend off of the existing lease. The proponent has applied for a lease modification to enlarge Federal Phosphate Lease I–27512 to accommodate those operations. The application includes two tracts, the North Lease Modification and the South Lease Modification, both for the purpose of ore recovery. Subsequent to preparation of the DEIS, the proponent has also applied for a lease modification to Federal Phosphate Lease I–01441 to accommodate 18 acres of off-lease external overburden fill at Panel G. The environmental impacts of mining off of the existing leases, within the lease modification areas, are analyzed in the FEIS.

Many of these proposed activities would occur within Forest Service Inventoried Roadless Areas. Inventoried Roadless Areas are managed according to local land use plans and Forest Service roadless management regulations, such as the Roadless Area Conservation Rule (RACR). The Agency Preferred Alternative identified in the FEIS may be modified in the Record of Decision to comply with laws and regulations applicable at that time.

The agency Preferred Alternative would approve mining both leases described as Panel F and Panel G. To accommodate the proposed off-lease mining, BLM would approve the lease modifications to I–27512 (Panel F). As described in Mining Alternative D, BLM would require construction of a Store and Release cover system to reduce the infiltration of water through seleniferous backfill and external seleniferous overburden fills. The FS would require power line placement on poles along the haul road corridor, as described in Mining Alternative E. The transportation route between Panel F and the existing mine would be constructed according to the Proposed Action. The agency Preferred Transportation Alternative to access Panel G is the Proposed Action, Panel G West Haul/Access Road. The environmentally preferable transportation alternative would be Alternative 2, the East Haul/Access Road. The Alternative 2 road alignment crosses a portion of private land. Implementation of this alternative is contingent upon the proponent's ability to secure an easement across the private land. Access to Panel G is not required for several years. During that time, if Simplot and the private land holder were to come to a mutual agreement that would provide Simplot an easement, the East Haul/Access Road would replace the Panel G West Haul/Access Road.

Alternatives

Issues were identified for the proposed mining of Panels F and G by the agencies and by the public during the scoping process. They include potential effects on: ground water, surface water, geology and minerals, air quality and noise, soils, vegetation, wetlands, wildlife, fisheries and aquatic life, livestock grazing, recreation, Inventoried Roadless Areas, socio-economics, visual resources, cultural resources, and Tribal Treaty Resources. Alternatives to the proposed action were developed to address these issues.

Mining alternatives include mining without one or both lease modifications to Panel F, no external seleniferous overburden fills, no external overburden fills at all, construction of an infiltration-reducing cover over seleniferous material, constructing the power line only within proposed disturbance, and using generators in Panel G instead of a power line. The transportation alternatives include one variation on the haul road between Panel F and the existing mine, two variations of a haul road from Panel G located east of the project area, a more direct haul road from Panel G to Panel F, a variation of the proposed West Haul Road, and using a conveyor system to transport ore from Panel G to the existing mill. Two variations of the conveyor alternative are assessed with alternate routes for moving personnel and equipment between Panel G and the existing mine.

Jeff Cundick,

Acting District Manager, Idaho Falls District, Bureau of Land Management.

Larry Timchak,

Forest Supervisor, Caribou-Targhee National Forest.

[FR Doc. 07–5333 Filed 10–25–07; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–920–1320–EL]

Powder River Regional Coal Team Activities: Notice of Public Meeting in Casper, WY

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: The Powder River Regional Coal Team (RCT) has scheduled a public meeting for December 6, 2007, to review current and proposed activities in the Powder River Coal Region and to review pending coal lease applications (LBA).

DATES: The RCT meeting will begin at 9 a.m. MST on December 6, 2007. The meeting is open to the public.

ADDRESSES: The meeting will be held at the Wyoming Oil and Gas Conservation Commission, 2211 King Boulevard, Casper, Wyoming.

FOR FURTHER INFORMATION CONTACT: Robert Janssen, Regional Coal Coordinator, BLM Wyoming State Office, Division of Minerals and Lands, 5353 Yellowstone Road, Cheyenne, Wyoming 82009: telephone 307–775–6206 or Rebecca Spurgin, Regional Coal Coordinator, BLM Montana State Office, Division of Resources, 5001 Southgate Drive, Billings, Montana 59101: telephone 406–896–5080.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to discuss pending coal lease by applications (LBA's) in the Powder River Basin as well as other Federal coal related actions in the region. Specific coal lease applications and other matters for the RCT to consider include:

1. The Porcupine LBA, a lease application filed by BTU Western Resources on September 27, 2006, which is adjacent to the North Antelope-Rochelle mine. This application was reviewed by the RCT at a public meeting on January 18, 2007. At that time, approximately 5,116 acres and 598 million tons of Federal coal were included in the application. The applicant now wishes to amend this application. More details will be presented at the meeting. The RCT needs to consider the BLM processing schedule for the Porcupine LBA.

2. The BLM is doing a coal review study in the Powder River Basin. The results of this study will be used in the preparation of coal related NEPA documents in the Powder River coal region. The RCT will be updated on the progress and results of this study.

3. Update on U.S. Geological Survey coal inventory work.

4. Update on BLM land use planning efforts in the Powder River Basin of Wyoming and Montana.

5. Other Coal Lease Applications and issues that may arise prior to the meeting.

The RCT may generate recommendation(s) for any or all of these topics and other topics that may arise prior to the meeting date.

The meeting will serve as a forum for public discussion on Federal coal management issues of concern in the Powder River Basin region. Any party interested in providing comments or data related to the above pending applications, or any party proposing other issues to be considered by the RCT, may either do so in writing to the State Director (922), BLM Wyoming State Office, 5353 Yellowstone Road, Cheyenne, WY 82009, no later than November 21, 2007, or by addressing the RCT with his/her concerns at the meeting on December 6, 2007.

The draft agenda for the meeting follows:

1. Introduction of RCT Members and guests.

2. Approval of the Minutes of the January 18, 2007 Regional Coal Team meeting held in Casper, Wyoming.

3. Coal activity since the last RCT meeting.

4. Industry Presentations on Lease Applications: BTU Western Resources, Modification of the Porcupine LBA.

5. BLM presentation on Powder River Basin coal review study.

6. U.S. Geological Survey presentation on Coal Inventory.

7. BLM land use planning efforts.

8. Other pending coal actions and other discussion items that may arise.

9. Discussion of the next meeting.

10. Adjourn.

Dated: October 22, 2007.

Robert A. Bennett,

State Director.

[FR Doc. E7–21145 Filed 10–25–07; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

National Park Service

Draft Environmental Impact Statement/ Comprehensive Management Plan; Ala Kahakai National Historic Trail County of Hawaii, State of Hawaii; Notice of Availability

SUMMARY: Pursuant to § 102(2)(C) of the National Environmental Policy Act of 1969 (Pub. L. 91–190, as amended), and the Council on Environmental Quality Regulations (40 CFR part 1500–1508), the National Park Service, Department of the Interior, has prepared a Draft Comprehensive Management Plan and programmatic Environmental Impact Statement identifying and evaluating two alternatives to current administration and management of the Ala Kahakai National Historic Trail. These alternatives respond to the National Trails System Act (16 U.S.C. 1241–1251), NPS planning requirements, and the issues identified during public scoping. They address trail administration and management, cultural and natural resource protection, and use of the trail by local residents, Native Hawaiians, and the visiting public.

When approved, the comprehensive management plan will guide, for approximately 15 years, the National Park Service in administering, preserving, protecting, developing, managing, and maintaining the 175-mile trail which includes portions of the ancient and historic ala loa (long trail; coastal trail around the island). The EIS compares baseline conditions of a ''no action'' alternative with potential impacts and two ''action'' alternatives and, where appropriate, suggests mitigation measures to reduce the intensity of the potential effect or to avoid the potential effect. Three other preliminary alternatives were considered but rejected because they did not achieve the objectives of the plan or were infeasible. An ''environmentally preferred'' alternative is also identified.

Background: The National Park Service (NPS) administers the Ala Kahakai National Historic Trail (NHT), added to the National Trails System by the U.S. Congress on November 13, 2000. The legislation authorizing the Ala Kahakai NHT identifies an approximately 175-mile portion of prehistoric ala loa (long trail) and other trails on or parallel to the seacoast extending from Upolu Point on the north tip of Hawaii Island down the west coast of the island around South Point to the east boundary of Hawaii Volcanoes National Park. The Ala Kahakai NHT combines surviving elements of the ancient ala loa with segments of later government trails (alanui aupuni), which developed on or parallel to the traditional routes, and more recent pathways and roads that create links between the historic segments.

The purposes of the Ala Kahakai NHT, derived from the legislative history, the Feasibility Study, and the public scoping phase completed in 2003, are to:

• Preserve, protect, reestablish as necessary, and maintain a substantial portion of the ancient ala loa and associated resources and values, along with linking trails on or parallel to the shoreline on Hawaii Island, and

• Provide for a high quality experience, enjoyment, and education (guided by Native Hawaiian protocol and etiquette) while protecting the trail's natural and cultural heritage and respecting private and community interest.

Federal ownership of the Ala Kahakai NHT is limited to the trail alignment within the four national parks it links: Pu'ukohola Heiau National Historic Site, Kaloko-Honokohau National Historical Park (NHP), Pu'uhonua o Honaunau NHP, and Hawaii Volcanoes National Park. Approximately 17% of the NHT is within the boundaries of these national parks. With trail authorization, these trail segments become federally protected components of the NHT, in compliance with § 3(a)(3) of the National Trails System Act.

The National Trails System Act, as amended, requires the preparation of a comprehensive management plan (CMP) for each new trail in the system. The CMP is intended to provide direction for natural and cultural resource preservation, education, and trail user experience of the Ala Kahakai NHT over the next 15 years. It considers the trail in its entirety. It identifies the necessity of community partnerships to protect trail resources and provide appropriate trail user services. As a partnership endeavor, the success of this plan is not solely determined by the NPS; rather its success rests with the will and preservation of other local government agencies, communities, organizations, neighborhood associations, and individuals who have the capacity and desire to implement actions within this plan.

Proposed Plan and Alternatives: Alternative C (both the agency-preferred as well as the ''environmentally preferred'' alternative), is based on the traditional Hawaiian trail system in which multiple trail alignments within the ahupua'a (mountain to sea land division) are integral to land use and stewardship. Within the planning period of 15 years, the goal would be to complete the linear trail within the priority zone from Kawaihae to Pu'uhonau o Honaunau NHP (73 miles) and to protect other segments outside of that area as feasible. In addition, on publicly-owned lands the Ala Kahakai NHT would include inland portions of the ala loa or other historic trails that run lateral to the shoreline and would be connected to ancient or historic mauka-makai (mountain to sea) trails that would have traditionally been part

of the ahupua'a system. Through an agreement, the state of Hawaii could convey to the NPS a less-than-fee management interest in trail segments that are state-owned under the Highways Act of 1892 within the Ala Kahakai NHT corridor. The NPS would then be responsible for managing these segments and federal law would fully apply. However, in cooperation with the NPS, local communities of the ahupua'a would be encouraged to take responsibility for trail management using the traditional Hawaiian principles of land management and stewardship. The NPS would offer technical assistance and limited financial assistance to these management partners. Partnerships with state and county agencies, community organizations, and private individuals would help protect trail resources and provide appropriate trail user services. The Ala Kahakai Trail Association would be expected to be robust enough play a major part in trail management, promotion, and funding. An auto tour would be completed that would lead visitors to 18 sites associated with the trail.

Alternative A constitutes the ''No Action'' alternative, under which existing programs, facilities, staffing, and funding would generally continue at their current levels. The Ala Kahakai NHT would consist of trail segments within the four national parks through which it passes and only a few other segments, most likely on state lands. A continuous trail, as recommended in the Feasibility Study, would be the goal but would not be achievable, even in the long-term. An auto tour would be completed. Recreation along the trail and interpretation of its history would generally be limited to these sites.

Alternative B proposes the completion of a single continuous trail composed of unaltered or verified ancient and historic portions of the ala loa linked as needed by later pre-1892 trails, pathways, and modern connector trails. Within the planning period of 15 years, the goal would be to complete the linear trail within the priority zone from Kawaihae to Pu'uhonua o Honaunau NHP and to protect other segments outside of that area as feasible. In the long term, cultural and natural resources along the entire trail tread and agreed-upon adjacent areas would be protected and interpreted to the public. The NPS would administer the trail, but management outside of the national parks would remain with the land managing agency or landowner. The NPS would offer technical assistance and limited financial assistance to these management partners. Partnerships with state and county agencies, the Ala Kahakai Trail Association, community organizations, and private individuals would help protect trail resources and provide appropriate trail user services. An auto tour would be completed.

Scoping Summary: On April 4, 2003, the NPS published the Notice of Intent formally initiating the conservation planning and environmental impact analysis process for the Ala Kahakai NHT comprehensive management plan; the scoping period extended through June 28, 2003. Over 1,830 public scoping meeting announcements were mailed using an address list that included hiking enthusiasts affiliated with E Man Na Ala Held, various legislators, the Caleche-Hanukkah N.P. contact list, and interested individuals, organizations, and agencies that provided their contact information to the trail staff. The NPS advertised meetings in West Hawaii Today and Hawaii Tribune-Herald. Large signs were posted on meeting days in high-visibility areas on adjacent roadways and on buildings where the meetings were held to encourage walk-by and drive-by participation. Meeting announcements also appeared in the Ala Kahakai NHT and E Man Na Ala Held newsletters. Altogether nine open house scoping meetings were hosted between March 22 and June 28, 2003. At the meetings, attendees were encouraged to submit formal input through a Mana'o Form, a questionnaire about how the trail should be managed. A total of 200 people representing the general public, private landowners, trail advocacy groups, native Hawaiian organizations, and state, county, and federal agencies attended these meetings. About 25 Mana'o Forms were returned to the trail office. In addition, the planning team met with numerous individuals, community groups, private landowners, and government agency representatives to understand their concerns and visions for the Ala Kahakai NHT. Using the information for all these sources, the planning team prepared draft versions of the purpose and significance statements, management prescriptions, and management alternatives.

Between July 2003 and March 2004, the planning team developed five preliminary alternatives for future management based on information gained from the scoping process: No Action, Single Ala Kahakai Trail alternative, Ahupua'a Trail Systems alternative, Historic Trail Clusters alternative, and Public Lands alternative. The NPS provided a booklet to the public describing these alternatives and inviting comment. In addition, the NPS conducted nine public meetings between April 17 and June 19, 2004, to gather comments on the alternatives. The comment period for the draft alternatives closed on June 25, 2004. Subsequently the planning team prepared a draft alternatives document that eliminated alternative E because it was favored in public meetings only as a step to completing the entire trail. Eventually, alternative D was eliminated for the same reason.

In December 2006, to ensure that issues were properly stated and addressed, an internal review draft of this document was sent to the four national parks on Hawaii Island, other National Park Service reviewers, and reviewers in Hawaii who have been involved in the study process and have knowledge of the Ala Kahakai NHT. These reviewers' comments were incorporated into the public review draft.

Commenting On The Draft EIS: Six public workshops on the proposed plan will be hosted during the week of November 5–10, 2007 at various locations on the island of Hawaii. Locations, dates, and other workshop details will be advertised by direct mailing and notices placed in the local newspapers. All interested individuals, organizations, and agencies will be encouraged to participate and provide comments, suggestions, and additional information. All written comments must be postmarked not later than 60 days following publication in the **Federal Register** by EPA of their notice of filing of the Draft EIS (as soon as this date can be confirmed it will be announced on the park's Web site, and included in workshop mailings).

Written comments on the Draft EIS/CMP should be addressed to Superintendent, Ala Kahakai NHT, 73–4786 Kanalani Street, #14, Kailua–Kona, HI 96740. Questions at this time regarding the comprehensive management plan and EIS planning process or inquiries about public meetings should be addressed to the superintendent either by mail or by telephone at (805) 326–6012. The document will be sent directly to those who have requested it, and will also be available at the park headquarters and local libraries, or electronically at *http://parkplanning.nps.gov/alka* (an electronic public comment form is also provided at this Web site). Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time.

While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Decision: Following careful analysis of public and agency comments on the Draft EIS, it is anticipated at this time that the final EIS would be available in winter of 2008. As a delegated EIS, the official responsible for the final decision is the Regional Director, Pacific West Region. A Record of Decision would not be prepared sooner than 30 days following release of the Final EIS/CMP; notice of the decision will be posted in the **Federal Register** and announced in local and regional newspapers. Following approval of the comprehensive management plan and EIS, the official responsible for undertaking implementation of the plan will be the Superintendent, Ala Kahakai National Historic Trail.

Dated: October 18, 2007.

George J. Turnbull,

Acting Regional Director, Pacific West Region.

[FR Doc. 07–5305 Filed 10–25–07; 8:45 am]

BILLING CODE 4312–52–M

DEPARTMENT OF THE INTERIOR

National Park Service

Final General Management Plan/ Environmental Impact Statement; Record of Decision; Flight 93 National Memorial, Pennsylvania

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of Availability of the Record of Decision for the Final General Management Plan/Environmental Impact Statement, Flight 93 National Memorial.

SUMMARY: Pursuant to Sec. 102(2)(C) of the National Environmental Policy Act of 1969, Pub. L. 91–190, 83 Stat. 852, 853, codified as amended at 42 U.S.C. 4332(2)(C), the National Park Service announces the availability of the Record of Decision for the Final General Management Plan and Environmental Impact Statement (Final GMP/EIS) for the Flight 93 National Memorial in Pennsylvania. On July 23, 2007, the Regional Director, Northeast Region, approved the Record of Decision for the project, selecting Alternative 2—Preferred Design Alternative, which was described on pages II–14 to II–23 of the Final GMP/EIS and announced to the public in a Notice of Availability published in the **Federal Register** on June 21, 2007.

The selected alternative and one other alternative, Alternative 1—No Action, were analyzed in the Draft and Final Environmental Impact Statements. Each alternative was evaluated as to how it would guide the development and future management of the national memorial over the next 15 to 20 years with regard to the following issues: (1) The types of management actions required for the development, protection and preservation of park resources; (2) The types and general intensities of development (including the memorial features, visitor facilities, transportation and access requirements) associated with the public enjoyment and use of the area, including general locations, timing of implementation and anticipated costs; (3) Visitor carrying capacities and implementation commitments for major aspects of the memorial; and (4) Potential modifications to the external boundaries of the park, if any, and the reasons for the proposed changes. The full range of foreseeable environmental consequences was assessed and disclosed for historic and cultural resources, natural resources, land use, transportation, socioeconomic impacts, visual and aesthetic impacts, energy requirements, and public health and safety.

The NPS has selected Alternative 2 because it best fulfills the goals of the Flight 93 National Memorial's Missions Statement, as well as the purpose and intent of the Flight 93 National Memorial Act. The selected alternative commemorates the actions of the passengers and crew by creating a designed memorial landscape, which blends with the contour of the land and enhances the physical features of the site. It protects the final resting places of the passengers and crew and places special attention on providing an appropriate setting for the memorial. A new visitor facility will provide for interpretive exhibits, public education and outreach, and visitor services. The public will have a broader range of opportunities to learn about the deeds of the passengers and crew members and the events that occurred on September 11, 2001. The selected alternative also provides a venue for visitors to get closer to the crash site while removing parking and other visitor support facilities from the views around the crash site. Under the selected alternative, visitor traffic will be contained within the site and removed from the neighboring villages to create safer roadway conditions and significantly improve conditions for residents living along these routes. The selected alternative will not result in the impairment of resources and values. The construction costs to build the memorial features and the related infrastructure would be shared through a partnership involving the public, the Commonwealth of Pennsylvania, and the federal government.

The Record of Decision includes a statement of the decision made, synopses of other alternatives considered, the basis for the decision, a finding of no impairment of park resources and values, and an overview of public involvement in the decision-making process. This decision is the result of a public planning process that began with publication of a Notice of Intent in the **Federal Register** on December 10, 2003. The official responsible for this decision is the NPS Regional Director, Northeast Region.

ADDRESSES: The Record of Decision for the Final GMP/EIS for the Flight 93 National Memorial is available online at *http://www.flight93memorialproject.org* or *http://www.planning.nps.gov/plans.cfm*. Copies may be obtained by contacting the Superintendent, National Parks of Western Pennsylvania, National Park Service, 109 W. Main St., Suite 104, Somerset, PA 15501.

FOR FURTHER INFORMATION CONTACT: Joanne Hanley, Superintendent, National Parks of Western Pennsylvania, National Park Service, 109 W. Main St., Suite 104, Somerset, PA 15501, phone (814) 443–4557, *joanne_hanley@nps.gov*.

SUPPLEMENTARY INFORMATION: The *Flight 93 National Memorial Act* (Pub. L. 107–226; 116 Stat. 1345), enacted on September 24, 2002, authorized ''a national memorial to commemorate the passengers and crew of Flight 93 who, on September 11, 2001, courageously gave their lives thereby thwarting a planned attack on our Nation's Capital.'' This legislation enabled the creation and development of the new Flight 93 National Memorial in Stonycreek Township, Somerset County, Pennsylvania and specifically designated the crash site of Flight 93 as the site to honor the passengers and crew of Flight 93. Pub. L. 107–226 authorized the Secretary of the Interior to administer the Flight 93 National Memorial as a unit of the national park system. This Act also created the Flight 93 Advisory Commission and charged it with: (1) Advising the Secretary on the boundary of the memorial site; (2) submitting to the Secretary a report containing recommendations for the planning, design, construction, and long-term management of a permanent memorial at the crash site; and (3)

advising the Secretary in the development of a management plan for the site.

On January 14, 2005, the Secretary of the Interior approved a boundary recommendation for the memorial presented by the Flight 93 Advisory commission. The details of the boundary were published in the **Federal Register** (70 FR 13538) on March 21, 2005. The boundary includes 1,355 acres, which comprises the crash site, the debris field and areas where human remains were found, and lands necessary for viewing and accessing the national memorial. Approximately 907 additional acres comprise the perimeter viewshed, which would be protected through conservation or scenic easements acquired by partners, nonprofit organizations or other governmental agencies.

Four partner organizations (the Partners) participated in the planning of a permanent memorial for Flight 93: (1) The Flight 93 Advisory Commission, (2) the Families of Flight 93, a nonprofit organization, (3) the Flight 93 Memorial Task Force, and (4) the National Park Service, the Federal agency responsible for compliance with the National Environmental Policy Act of 1969 (Pub. L. 91–190, as amended). On September 11, 2004, the Partners opened a two-stage international design competition to solicit a broad range of concepts for the design of the new memorial. During Stage 1 of the competition, five top designs were selected by a jury of professionals, family members and local leaders after extensive public exhibit of the designs. A Stage 2 design jury selected the final design that best achieved the mission of the new memorial. The selected design was announced to the public on September 7, 2005, and is the basis of the preferred alternative in the Draft and Final GMP/EIS. After public announcement of the final design, the National Park Service received comments criticizing the design's principal landscape feature, a curved allée or pathway lined with red maple trees, comparing it to an Islamic crescent symbol. The design was refined and again presented to the public in November 2005. The design refinements were generally well-received by the public; however, a sector of the public continued to assert that the design contained Islamic symbolism. In response, the partners met with religious scholars, design professionals, and other family members and toured the site with the principal critic of the design. At the conclusion of these activities and consultations, it was determined that the perceptions of religious symbolism in the design had been adequately addressed by the architect and that the details of the design do not affect the Final GMP/EIS. The NPS, along with the other Partners, were satisfied that the design properly honors the passengers and crew and that the refinements showed the architects' sensitivity and responsiveness to public comments.

Dated: October 4, 2007.

Dennis R. Reidenbach,

Regional Director, Northeast Region, National Park Service.

[FR Doc. 07–5304 Filed 10–25–07; 8:45 am]

BILLING CODE 4312–25–M

DEPARTMENT OF THE INTERIOR

National Park Service

National Preservation Technology and Training Board—National Center for Preservation Technology and Training: Meeting

AGENCY: National Park Service, U.S. Department of the Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act (5 U.S.C. Appendix (1988)), that the Preservation Technology and Training Board (Board) of the National Center for Preservation Technology and Training (NCPTT), National Park Service will meet on Friday and Saturday, November, 2–3, 2007, in San Juan, Puerto Rico.

The Board was established by Congress to provide leadership, policy advice, and professional oversight to the National Park Service's NCPTT in compliance with Section 404 of the National Historic Preservation Act of 1966, as amended, (16 U.S.C. 470x–2(e)).

Location: The Board will meet at the Caribe Hilton Hotel, Los Rosales Street, Gerónimo Grounds, San Juan, Puerto Rico 00901—telephone (787) 721–0303.

DATES: The meeting will run from 9 a.m. to 5 p.m. on November 2 and from 9 a.m. to 12 p.m. on November 3.

SUPPLEMENTARY INFORMATION: The Board's meeting agenda will include: review and comment on NCPTT FY2007 accomplishments and operational priorities for FY2008; FY2007 and FY2008 NCPTT budget and initiatives; proposed Wingspread Conference on Sustainability in Preservation; revitalization of the Friends group, and Board workgroup reports.

The Board meeting is open to the public. Facilities and space for accommodating members of the public are limited, however, and persons will be accommodated on a first come, first served basis. Any member of the public may file a written statement concerning any of the matters to be discussed by the Board.

Minutes of the meeting will be available for public inspection no later than 90 days after the meeting at the office of the Executive Director, National Center for Preservation Technology and Training, National Park Service, U.S. Department of the Interior, 645 University Parkway, Natchitoches, LA 71457—telephone (318) 356–7444.

An exceptional set of circumstances in the approval and transmission of this notice has resulted in the publication of the notice less than 15 days before the date of the meeting. The National Park Service has made extraordinary efforts to provide notification to all Board members and to the public. The meeting is being co-located with the Association for Preservation Technology (APT) meeting, and it would cause an undue burden on the Board members to reschedule the meeting.

FOR FURTHER INFORMATION CONTACT: Mr. Kirk A. Cordell, Executive Director, National Center for Preservation Technology and Training, National Park Service, U.S. Department of the Interior, 645 University Parkway, Natchitoches, LA 71457—telephone (318) 356–7444. In addition to U.S. Mail or commercial delivery, written comments may be sent by fax to Mr. Cordell at (318) 356–9119.

Dated: October 22, 2007.

Janet Snyder Matthews,

Associate Director for Cultural Resources.

[FR Doc. E7–21084 Filed 10–25–07; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Realty Action for Proposed Land Exchange

AGENCY: National Park Service, Interior.

SUMMARY: Proposed exchange of federally-owned lands for privately-owned lands in Lake Clark National Park and Preserve. The federally-owned lands are located in the Kenai Peninsula Borough, Alaska. The private lands are located in the Lake and Peninsula Borough, Alaska.

DATES: We must receive written comments on the proposed exchange by December 10, 2007.

ADDRESSES: Detailed information concerning this exchange is available from the Superintendent, Lake Clark National Park and Preserve, 240 W. 5th Avenue, Anchorage, Alaska 99501.

SUPPLEMENTARY INFORMATION: The following described federally-owned land has been determined to be suitable for disposal by exchange. The authority for this exchange is section 1302(h) of the Alaska National Interest Lands Conservation Act (ANILCA) of December 2, 1980, 16 U.S.C. 3192(h). The federal land which is proposed for disposal is within the boundary of the Lake Clark National Park and Preserve. It is located approximately 2 miles southwesterly of the mouth of Silver Salmon Creek and contains approximately 4.55 acres. The land has been surveyed for cultural resources and endangered and threatened species. These reports are available upon request from the Superintendent, Lake Clark National Park and Preserve at the address set forth above. Title to the above land will be conveyed in fee simple with covenants and restrictions that prohibit for-profit selling of services, industrial uses and commercial development. The covenants also limit development and occupancy of the parcel and require that future development be visually compatible with surrounding park and preserve lands. Conveyance of the land by the United States will be done by patent.

In exchange for the land identified above the United States of America will acquire U.S. Survey 8481, Alaska, a 79.98-acre parcel on the southern shore of Lake Clark at Sucker Bay, approximately 16.5 miles southwesterly of the village of Port Alsworth, and approximately 7.5 miles northwesterly of Nondalton in fee simple with no reservations. The value of the properties exchanged shall be determined by a current fair market value appraisal. If the appraised value of the Sucker Bay parcel is greater than the appraised value of the Silver Salmon Creek parcel, the parties will complete the exchange, subject to approval of title to the Sucker Bay parcel by the Department of the Interior, Regional Solicitor. An environmental assessment of the proposed action was completed in January 2007 and a Finding of No Significant Impact approved on March 26, 2007.

For a period of 45 calendar days from the date of this notice, interested parties may submit comments to the above address. Comments will be evaluated and this action may be modified or vacated accordingly. In the absence of any action to modify or vacate, this realty action will become the final determination of the Department of the Interior.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: October 18, 2007.

Marcia Blaszak,

Regional Director, Alaska.

[FR Doc. E7–21085 Filed 10–25–07; 8:45 am]

BILLING CODE 4310–T6–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Seventh Public Meeting for Reclamation's Managing for Excellence Project

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of a public meeting and announcement of subsequent meetings to be held.

SUMMARY: The Bureau of Reclamation is holding a meeting to inform the public about the *Managing for Excellence* project. This meeting is the fourth to be held in 2007 to inform the public about the action items, progress, and results of the *Managing for Excellence* project and to seek broad public input and feedback. Subsequent meetings are anticipated and will be held in collaboration with the public.

DATES: November 7, 2007, 1:30 p.m. to 6 p.m.

ADDRESSES: Hyatt Regency Albuquerque, 330 Tijeras, Albuquerque, New Mexico, 87102.

FOR FURTHER INFORMATION CONTACT: Debbie Byers at (303) 445–2790.

SUPPLEMENTARY INFORMATION: The *Managing for Excellence* project will identify and address the specific 21st Century challenges Reclamation must meet to fulfill its mission to manage, develop, and protect water and related resources in an environmentally and economically sound manner in the interest of the American public. This project will examine Reclamation's core capabilities and the agency's ability to respond to both expected and unforeseeable future needs in an innovative and timely manner. This project will result in essential changes in a number of key areas, which are outlined in, *Managing for Excellence*—An Action Plan for the 21st Century Bureau of Reclamation. For more information regarding the project, Action Plan, and specific actions being taken, please visit the *Managing for Excellence* Web site at *http://www.usbr.gov/excellence.*

Registration

Although you may register the day of the workshop beginning at 12 p.m., we highly encourage you to register prior to the date of the meeting online at *http://www.usbr.gov/excellence,* or by phone at 303–445–2935.

Dated: October 16, 2007.

Ryan Serote,

Acting Deputy Commissioner for External and Intergovernmental Affairs.

[FR Doc. E7–21135 Filed 10–25–07; 8:45 am]

BILLING CODE 4310–MN–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–601]

In the Matter of Certain 3G Wideband Code Division Multiple Access (WCDMA) Handsets and Components Thereof; Notice of Commission Decision Not To Review an Initial Determination Granting Complainants' Motion To Substitute Parties

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'') (Order No. 9) issued by the presiding administrative law judge (''ALJ'') granting complainants'' motion to substitute parties in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Eric Frahm, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–3107. Copies of non-confidential 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. 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) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by

contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on April 27, 2007, based on a complaint filed by InterDigital Communications Corp. of King of Prussia, Pennsylvania and InterDigital Technology Corp. of Wilmington, Delaware (collectively, ''InterDigital''). 72 FR. 21049 (April 27, 2007). The complaint, as amended and supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain 3G wideband code division multiple access (WCDMA) handsets and components thereof by reason of infringement of claims 1, 2, 7–10, 14, 15, 21, 22, 24, 30–32, 34, 35, 46, 47, 49, 59, and 60 of U.S. Patent No. 7,117,004; claims 7 and 10 of U.S. Patent No. 6,674,791; claims 1–4 of U.S. Patent No. 6,693,579; and claims 1, 3, and 6–12 of U.S. Patent No. 7,190,966. The complaint further alleges the existence of a domestic industry as required by section 337(a)(2). The notice of investigation named Samsung Electronics Co., Ltd. of Seoul, Korea; Samsung Electronics America, Inc. of Ridgefield Park, New Jersey; and Samsung Telecommunications America LLC of Richardson, Texas (collectively, ''Samsung'') as respondents.

On September 12, 2007, InterDigital filed a motion to substitute parties. Specifically, InterDigital moved to substitute one of the co-complainants, InterDigital Communications Corporation, with InterDigital Communications, LLC. InterDigital stated in its motion that the substitution will not substantively affect the investigation, and the Commission investigative attorney made no objection. Likewise, Samsung made no objection, subject to certain conditions.

On September 27, 2007, the ALJ granted InterDigital's motion to substitute parties, without conditions. No petitions for review were filed. The Commission has determined not to review the ALJ's ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 CFR 210.42).

Issued: October 22, 2007.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E7–21175 Filed 10–25–07; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

October 23, 2007.

The Department of Labor (DOL) hereby announces the submission of the following public information collection requests (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation; including among other things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or by contacting Darrin King on 202–693–4129 (this is not a toll-free number) / e-mail: *king.darrin@dol.gov.*

Interested parties are encouraged to send comments to the Office of Information and Regulatory Affairs, Attn: John Kraemer, OMB Desk Officer for the Occupational Safety and Health Administration (OSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–7316 / Fax: 202–395–6974 (these are not toll-free numbers), E-mail: *OIRA_submission@omb.eop.gov* within 30 days from the date of this publication in the **Federal Register**. In order to ensure the appropriate consideration, comments should reference the OMB Control Number (see below).

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Occupational Safety and Health Administration.

Type of Review: Extension without change of a previously approved collection.

Title: Concrete and Masonry Construction (29 CFR 1926, Subpart Q).

OMB Number: 1218–0095.

Affected Public: Private Sector: Business or other for-profits.

Estimated Number of Respondents: 468,600.

Estimated Total Burden Hours: 37,488.

Estimated Total Annual Costs Burden: $0.

Description: Construction firms engaged in the erection of concrete formwork are required to post warning signs/barriers in accordance with 29 CFR 1926.701(c)(2) to reduce exposure of non-essential employees to the hazards of post-tensioning operations. Paragraphs 29 CFR 1926.702(a)(2), (j)(1), and (j)(2) are general lockout/tagout measures to protect workers from injury associated with equipment and machinery.

Agency: Occupational Safety and Health Administration.

Type of Review: Extension without change of a previously approved collection.

Title: Storage and Handling of Anhydrous Ammonia (29 CFR 1910.111).

OMB Number: 1218–0208.

Affected Public: Private Sector: Business or other for-profits and Farms.

Estimated Number of Respondents: 2,030.

Estimated Total Burden Hours: 345.

Estimated Total Annual Costs Burden: $0.

Description: The container markings required by 29 CFR 1910.111 (the Standard) ensure that employers use only properly designed and tested containers and systems to store anhydrous ammonia; thereby preventing accidental exposure to employees. In addition, these requirements provide the most efficient means for an OSHA compliance officer to ensure that the containers are safe and in compliance with the Standard.

Darrin A. King,

Acting Departmental Clearance Officer.

[FR Doc. E7–21173 Filed 10–25–07; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

October 23, 2007.

The Department of Labor (DOL) hereby announces the submission the following public information collection requests (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation; including among other things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or by contacting Darrin King on 202–693–4129 (this is not a toll-free number)/e-mail: *king.darrin@dol.gov.*

Interested parties are encouraged to send comments to the Office of Information and Regulatory Affairs, Attn: Carolyn Lovett, OMB Desk Officer for the Employment Standards Administration (ESA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–7316/Fax: 202–395–6974 (these are not toll-free numbers), E-mail: *OIRA_submission@omb.eop.gov* within 30 days from the date of this publication in the **Federal Register**. In order to ensure the appropriate consideration, comments should reference the OMB Control Number (see below).

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Employment Standards Administration.

Type of Review: Extension without change of currently approved collection.

Title: Report of Construction Contractor's Wage Rates.

OMB Control Number: 1215–0046.

Form Number: WD–10.

Estimated Number of Respondents: 22,000.

Total Estimated Annual Burden Hours: 22,000.

Total Estimated Cost Burden: $0.

Affected Public: Private Sector: Business or other for-profits.

Description: The Form WD–10 is used by the U.S. Department of Labor to elicit construction project data from contractor associations, contractors and unions. The wage data is used to determine locally prevailing wages under the Davis-Bacon and Related Acts.

Agency: Employment Standards Administration.

Type of Review: Extension without change of currently approved collection.

Title: Application for Continuation of Death Benefit for Student.

OMB Control Number: 1215–0073.

Form Number: LS–266.

Estimated Number of Respondents: 43.

Total Estimated Annual Burden Hours: 22.

Total Estimated Cost Burden: $0.

Affected Public: Private Sector: Business or other for-profits.

Description: The information collected by the Form LS–266 is used by the Department's Office of Workers' Compensation Programs to assure that a claimant receives all of the benefits under the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 902 and 939) to which he/she may be entitled to receive. If the information were not collected, there would be no way to determine the proper status of a student and therefore his/her continued entitlement to benefits.

Darrin A. King,

Acting Departmental Clearance Officer.

[FR Doc. E7–21182 Filed 10–25–07; 8:45 am]

BILLING CODE 4510–CF–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Proposed Exemptions and Application Nos. Gastroenterology and Oncology Associates, P.A. Profit Sharing Plan and Trust (the Plan), D–11141; Wellington Management Company, LLP (Wellington Management), D–11343; GE Asset Management Incorporated, D–11389; Middleburg Trust Company (Middleburg), D–11405; and Citigroup, Inc. (Citigroup), D–11417

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Notice of proposed exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this **Federal Register** Notice. Comments and requests for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and requests for a hearing (at least three copies) should be sent to the Employee Benefits Security Administration (EBSA), Office of Exemption Determinations, Room N–5700, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. *Attention:* Application No. ____, stated in each Notice of Proposed Exemption. Interested persons are also invited to submit comments and/or hearing requests to EBSA via e-mail or FAX. Any such comments or requests should be sent either by e-mail to: *moffitt.betty@dol.gov,* or by FAX to (202) 219–0204 by the end of the scheduled comment period. The

applications for exemption and the comments received will be available for public inspection in the Public Documents Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N–1513, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Gastroenterology and Oncology Associates, P.A. Profit Sharing Plan and Trust (the Plan) Located in St. Petersburg, FL

[Application No. D–11141]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, will not apply to the proposed sale of certain shares of common stock (the Stock) issued by Alden Enterprises, Inc. (Alden), an unrelated party, by the individually directed account in the Plan (the Account) of Jayaprakash K. Kamath, M.D. (Dr. Kamath), to Geetha J. Kamath, M.D., (Mrs. Kamath), Dr. Kamath's spouse and a party in interest with respect to the Plan.

This proposed exemption is subject to the following conditions:

(a) The sale of the Stock by the Account to Mrs. Kamath is a one-time transaction for cash.

(b) The Stock is sold to Mrs. Kamath for a price that reflects the fair market value of the Stock, as determined by a qualified, independent appraiser (the Appraiser).

(c) The closing of the sale (the Closing Date) occurs at a time that is mutually agreed upon by Mrs. Kamath and the Plan trustees (the Trustees) within 30 days of the Department's approval of the final exemption.

(d) As of the Closing Date, the Appraiser reviews the assumptions previously made in determining the appraised value of the Stock to see whether there has been a 3% or more increase (Material Increase) in the fair market value of the Stock between December 31, 2006 (the Appraisal Date) and the Closing Date.

(e) If the Appraiser determines that there has been no Material Increase in the fair market value of the Stock on the Closing Date, the Appraiser issues a letter to the parties to the sale to such effect and the sale price of the Stock remains at the value determined on the Appraisal Date.

(f) If the Appraiser determines that there has been a Material Increase in the fair market value of the Stock, he advises the parties to the transaction, in writing, as to the increased value as of the Closing Date. Then, the sale price for the Stock is revised to reflect the increased value and the amount of such increase is paid to the Trustees by Mrs. Kamath following the receipt of the updated appraisal report from the Appraiser setting forth the increased value of the Stock.

(g) The sale proceeds from the transaction are credited to Dr. Kamath's Account simultaneously with the transfer of the Stock's title to Mrs. Kamath.

(h) The Account is not responsible for paying any fees, commissions, or other costs or expenses associated with the sale of the Stock.

(i) The terms and conditions of the Stock sale remain at least as favorable to the Account as the terms and conditions obtainable under similar circumstances negotiated at arm's length with an unrelated party.

Summary of Facts and Representations

1. Dr. Kamath is a gastroenterologist and oncologist and a 50% owner of Gastroenterology and Oncology Associates, P.A. (the Employer), the sponsor of the Plan. The Employer is a Florida corporation, which is located in St. Petersburg, Florida. The Employer is also owned 50% by Mrs. Kamath.

2. The Plan is a profit-sharing plan that was established by the Employer and provides for participant-directed investments. Dr. and Mrs. Kamath are the Plan Trustees. In addition, Dr. Kamath serves as the Plan Administrator. As of December 31, 2006, which is the most recent date Plan information is available, the Plan had 42 participants, one of whom included Dr. Kamath. Also as of December 31, 2006, the Plan had net assets available for benefits totaling $3,312,699. Of those assets, approximately $2,058,927 was held in Dr. Kamath's Account in the Plan.

3. Among the assets allocated to Dr. Kamath's Account are 42.84 shares of common stock, which constitute 14% of the issued and outstanding shares of Alden, a closely-held Florida corporation. Alden's primary business is the ownership and operation of a resort hotel on Florida's Gulf Coast. The property underlying the Stock consists of a 4.84 acre tract of land improved with 10 buildings that comprise the 142-unit beachfront hotel known as the ''Alden Beach Resort.'' The property is located at 5900 Gulf Boulevard, in the city of St. Pete Beach, Pinellas County, Florida.

None of the other shareholders of Alden are related to the Kamaths or the Employer. In addition, neither the Kamaths nor members of their family are officers or directors of Alden.

4. The Account acquired the Stock from Margaret Bradford, a retired, former Alden employee and an unrelated party, on September 15, 1983, for a cash purchase price of $150,000. The purchase price paid by the Account for the Stock was negotiated by the Trustees and Ms. Bradford. During its ownership of the Stock, the Account received $706,860 in dividends from 1983 until 2006. In addition, the Alden Beach Resort was refinanced in 1990, and the proceeds were distributed to the shareholders. The Account received $433,860 from the refinancing. The Account incurred no expenses or administrative costs in connection with its ownership of the Stock. As a result of the acquisition and holding of the Stock, the Account has experienced a

net gain of $990,720 [($706,860 + $433,860) − $150,000].

5. An administrative exemption is requested from the Department to allow Dr. Kamath's Account to sell the Stock to Mrs. Kamath. Following the sale, Mrs. Kamath proposes to transfer the Stock to a revocable trust for estate planning purposes. The sale price for the Stock will be based upon its independently appraised fair market value. The consideration for the Stock will be paid by Mrs. Kamath in cash. The Account will pay no fees or commissions in connection with the transaction.

6. The value of the Stock on December 31, 2006 was $899,640, according to a January 2, 2007 appraisal report that was prepared by Mr. James W. Brockardt, CBA, a qualified, independent appraiser. The Appraiser, who is the President of Brockardt Consulting Group, LLC, an independent appraisal firm located in Pennington, New Jersey, has worked in the area of securities valuation since 1975. The Appraiser represents that he is completely independent of the parties involved in the transaction and has no present or prospective interest in the Stock.

The Appraiser initially valued the Stock under both the Cost Approach and the Income Approach to valuation. Then, he determined a ''freely traded value'' based upon weighting 75% to the Cost Approach, and 25% to the Income Approach. This value was next discounted by 35% for lack of marketability. As a result of the calculation, the Appraiser determined that the Stock had an aggregate fair market value, on a minority interest basis, of $6,428,398, or a per share value, on a minority interest basis, of $21,000. Thus, the 42.84 shares of Stock held by Dr. Kamath's Account have a total fair market value of $899,640. In addition, the Stock represents approximately 25.74% of the Account's assets.

7. The proposed transaction is contingent upon the Department's issuance of a final exemption, on or before December 31, 2007, authorizing such transaction in accordance with an Agreement for Sale of Stock (the Stock Sale Agreement), to be entered into between Mrs. Kamath and the Trustees. In this regard, the Stock Sale Agreement provides that if the Department grants a final exemption approving the transaction, the closing of the transaction will occur within 30 days of such approval.

As of the Closing Date, the Appraiser will review the assumptions he previously made in determining the appraised value of the Stock to see whether there has been a 3% or more increase (i.e., a Material Increase) in the fair market value of the Stock between the Appraisal Date (i.e., December 31, 2006) and the Closing Date. If the Appraiser determines that there has been no Material Increase in the fair market value of the Stock on the Closing Date, he will issue a letter to Mrs. Kamath and the Trustees informing them that the sale price of the Stock will be the value determined on the Appraisal Date. On the other hand, if the Appraiser determines that there has been a Material Increase in the fair market value of the Stock, he will advise the parties to the transaction, in writing, as to the increased value as of the Closing Date. Then, the sale price for the Stock will be revised to reflect the increased value and the amount of such increase will be paid by Mrs. Kamath to the Trustees following the receipt of the updated appraisal report from the Appraiser. Mrs. Kamath will pay the Trustees for the Stock either in cash or by wire transfer.

If the Department does not grant a final exemption authorizing the proposed transaction by December 31, 2007, the transaction will be automatically rescinded and it will become null and void.

8. The Trustees represent that the transaction is in the best interest of the Account because the sale ensures that the Account will have greater liquidity and diversification since its assets will be invested in either marketable securities or assets that are traded on an established market. This will enable Dr. Kamath's interest to be rolled over to his individual retirement account upon his retirement. Also, given the lack of operating or financial control of a minority shareholder, such as the Account, the Trustees state that it would be difficult, if not impossible, to sell the Stock. Further, the Trustees explain that the transaction will enable Alden to make a Subchapter S corporation election.

9. It is represented that the transaction is protective of the Account because the fair market value of the property underlying the Stock will be updated on the Closing Date by the Appraiser. Further, the Account has not been required, nor will it be required, to pay any fees, commissions or other expenses or costs in connection with the subject transaction.

10. In summary, it is represented that the proposed transaction will satisfy the statutory requirements for an exemption under section 408(a) of the Act because:

(a) The sale of the Stock by the Account to Mrs. Kamath will be a one-time transaction for cash.

(b) The Stock will be sold to Mrs. Kamath for a price that reflects the fair market value of the Stock, as determined by the Appraiser on the Closing Date.

(c) The Closing Date of the transaction will occur at a time that is mutually agreed upon by Mrs. Kamath and the Trustees within 30 days of the Department's approval of the final exemption.

(d) The Appraiser will determine whether there has been a Material Increase in the fair market value of the Stock between the Appraisal Date and the Closing Date, and if so, he will make appropriate adjustments to the sale price in an updated appraisal report.

(e) Dr. Kamath's Account will not be responsible for paying any fees, commissions, or other costs or expenses associated with the sale of the Stock.

(f) The terms and conditions of the Stock sale will remain at least as favorable to the Account as the terms and conditions obtainable under similar circumstances negotiated at arm's length with an unrelated party.

Notice to Interested Persons

Because Dr. Kamath is the only participant in the Plan, it has been determined that there is no need to distribute the notice of proposed exemption to interested persons. Accordingly, comments and requests for a public hearing are due within thirty (30) days after the publication of the notice of proposed exemption in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Jan D. Broady of the Department, telephone (202) 693–8556. (This is not a toll-free number.)

Wellington Management Company, LLP (Wellington Management) and Its Subsidiaries (together, Wellington) Located in Boston, MA

[Application No. D–11343]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act (or ERISA) and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990).[1]

Section I. Covered Transactions

If the exemption is granted, the restrictions of section 406(a)(1)(A) and (D) of the Act and the sanctions

[1] For purposes of this proposed exemption, references to provisions of Title I of the Act, unless otherwise specified, refer also to the corresponding provisions of the code.

resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) and (D) of the Code, shall not apply (1) retroactively, from January 1, 2001 through December 31, 2003, and (2) prospectively, from the date the notice granting the final exemption is published in the **Federal Register**, to—

(A) The acquisition, from an offshore corporation (the Offshore Corporation) of certain non-voting equity securities (Shares), which represent interests in the economic value of the Offshore Corporation by an ERISA-covered client plan (the Client Plan), where the Offshore Corporation is a party in interest with respect to the Client Plan, due to the ownership of all of the voting equity shares (Manager Shares) of the Offshore Corporation by Wellington Global Administrator, Ltd. (Wellington Global Administrator), a subsidiary of Wellington Management, which is (or may become) a fiduciary and a service provider with respect to the Client Plan; and

(B) The redemption of the Client Plan's Shares by the Offshore Corporation either in cash or in kind.

Section II. Conditions

This proposed exemption is conditioned upon adherence to the material facts and representations described herein and upon satisfaction of the following conditions, which apply both retroactively and prospectively, unless otherwise excepted:

(a) All decisions to acquire or redeem Shares have been made or are made on behalf of the Client Plan by an authorized fiduciary, which is independent of Wellington and the applicable Offshore Corporation.

(b) At the time of acquisition of Shares from an Offshore Corporation, each Client Plan either had or has assets at least equal to $100 million.

(1) In the case of a master trust that holds assets of multiple related Client Plans maintained by a single employer or a controlled group of employers, as defined in section 407(d)(7) of the Act, this requirement is satisfied if the master trust has aggregate assets at least equal to $100 million (assuming the fiduciary responsible for making the investment decision is the Client Plan sponsor or an affiliate of the Client Plan sponsor).

(2) In the case of a pooled fund (e.g., a group trust) whose assets are ''plan assets'' subject to the Act, this requirement is satisfied as long as either (i) the pooled fund has at least $100 million in aggregate assets and the fiduciary making the investment decision is unrelated to Wellington and manages at least $200 million in assets (exclusive of the aggregate assets invested in the Offshore Corporations); or (ii) at least 50 percent of the units of beneficial interest in the pooled fund are held by Client Plans, each of which has total net assets of at least $100 million.

(c) Wellington has not provided and does not provide investment advice (within the meaning of 29 CFR 2510.3–21(c)), nor is it a fiduciary with respect to any Client Plan's investment in an Offshore Fund.

(d) All acquisitions and redemptions of Shares by a Client Plan have been made or are made for fair market value, determined as follows:

(1) Equity securities have been valued or are valued at their last sale price or official closing price on the market on which such securities primarily trade using sources independent of Wellington and the issuer. If no sales occurred on such day, equity securities are valued at the last reported independent ''bid'' price or, if sold short, at the last reported independent ''asked'' price.

(2) Fixed income securities have been valued or are valued on either the basis of ''firm quotes'' obtained at the time of the acquisition or redemption of Shares from U.S.-registered or foreign broker-dealers, which are registered and subject to the laws of their respective jurisdiction, which quotes reflect the share volume involved in the transaction, or on the basis of prices provided by independent pricing services that determine valuations based on market transactions for comparable securities and various relationships between such securities that are generally recognized by institutional traders.

(3) Options have been valued or are valued at the mean between the current independent ''bid'' price and the current independent ''asked'' price or, where such prices are not available are valued at their fair value in accordance with Fair Value Pricing Practices by Wellington Management's pricing committee, which utilizes a set of defined rules and an independent review process.

(4) If current market quotations are not readily available for any investments, such investments have been valued or will be valued at their fair value by Wellington Management's pricing committee in accordance with Fair Value Pricing Practices.

(e) A Client Plan's Shares have been redeemed or may be redeemed, in whole or in part, without the payment of any redemption fee or other penalty, on a pre-specified, periodic (not longer than semi-annual) basis, upon no more than 45 days' advance notice, except for a one-year lock-up period imposed on new investors.

(f) Redemptions of Shares in an Offshore Corporation by a Client Plan have been made or are made in cash unless:

(1) A Client Plan consents to such in kind redemption; or

(2) Wellington requires that such redemption be made in kind on a pro rata basis to protect the best interests of the Offshore Fund and the remaining investors, including other Client Plan investors.

(g) In advance of the initial investment by a Client Plan in an Offshore Corporation's Shares, the independent fiduciary of a Client Plan has received or receives—

(1) A copy of the proposed exemption and the final exemption. (This disclosure provision applies to the prospective exemptive relief described herein.)

(2) An offering memorandum describing the relevant Offshore Fund(s), as well as the relevant investment objectives, fees and expenses and redemption and valuation procedures; and

(3) All reasonably available relevant information as such independent fiduciary may request.

(h) On an ongoing basis, Wellington has provided or provides a Client Plan with the following information:

(1) Unaudited performance reports at the end of each month;

(2) Audited annual financial statements and access to a protected internet site; and

(3) Client services group assistance for any investor inquiries.

(i) No commission or sales charge has been assessed or is assessed against the Client Plan in connection with its acquisition of an Offshore Corporation's Shares.

(j) Not more than 10% of the assets of the Client Plan has been invested or is invested, in the aggregate, in Shares of all Offshore Corporations (determined at the time of any acquisition of such Shares) and not more than 5% of the assets of the Client Plan has been indirectly invested or is invested, in the aggregate, in any one offshore fund (the Offshore Fund), a separate collective investment vehicle underlying an Offshore Corporation, (also determined at the time of any acquisition of an interest in such Offshore Fund by such Client Plan).

(k) For prospective transactions only, each Offshore Corporation, each Offshore Fund, Wellington Management Investment, Inc. (Wellington

Management Investment), Wellington Global Holdings, Ltd. (Wellington Global Holdings), Wellington Hedge Management, LLC (Wellington Hedge Management), and Wellington Global Administrator—

(1) Has agreed to submit to the jurisdiction of the federal and state courts located in the Commonwealth of Massachusetts;

(2) Has agreed to appoint an agent for service of process in the United States, which may be an affiliate (the Process Agent);

(3) Has consented to service of process on the Process Agent; and

(4) Has agreed that any enforcement by a Plan of its rights pursuant to this exemption will, at the option of the Plan, occur exclusively in the United States courts.

(l) For prospective transactions only, Wellington maintains in the United States for a period of six years from the date of the covered transactions, such records as are necessary to enable the persons described in paragraph (m) of this Section II to determine whether the conditions of this exemption were met, except that:

(1) If the records necessary to enable the persons described in paragraph (m) to determine whether the conditions of the exemption have been met are lost or destroyed, due to circumstances beyond the control of Wellington, then no prohibited transaction will be considered to have occurred solely on the basis of the unavailability of those records; and

(2) No party in interest other than Wellington shall be subject to the civil penalty that may be assessed under section 502(i) of the Act or to the taxes imposed by section 4975(a) and (b) of the Code if the records have not been maintained or are not available for examination as required by paragraph (m) below.

(m)(1) Except as provided in paragraph (m)(2) of this Section II and notwithstanding the provisions of subsections (a)(2) and (b) of section 504 of the Act, the records referred to above in paragraph (l) of this Section II are unconditionally available for examination during normal business hours at their customary location to the following persons or an authorized representative thereof:

(i) Any duly authorized employee or representative of the Department or the Internal Revenue Service (the Service);

(ii) Any fiduciary of a Client Plan; or

(iii) Any participant or beneficiary of a Client Plan or any duly authorized employee or representative of such participant or beneficiary.

(2) None of the persons described above in paragraphs (ii) and (iii) of this paragraph (m)(1)(ii) and (iii) of this Section II shall be authorized to examine trade secrets of Wellington, or any commercial or financial information, which is privileged or confidential.

Section III. Definitions

(a) The term ''Wellington'' means Wellington Management Company, LLP and its subsidiaries.

(b) An ''affiliate'' of Wellington means—

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) Any officer, director, employee, relative, or partner in any such person; and

(3) Any corporation or partnership of which such person is an officer, director, partner, or employee.

(c) The term ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(d) The term ''Offshore Corporation'' means —

(1) WMIB;

(2) Any future expansion of WMIB that includes an additional class of securities or an additional Offshore Fund that is organized as a Bermuda limited partnership, which corresponds to the new WMIB class that is established by Wellington pursuant to the WMIB structure, and conforms to the same conditions, rules and regulations described in this exemption;

(3) Archipelago; or

(4) Any future ''fund of funds'' investment vehicle that is formed by Wellington under Bermuda law and is set up in substantially the same manner as Archipelago, with the same management structure, and conforms to the same conditions, rules and regulations described in this exemption.

(e) The term ''Offshore Fund'' means a collective investment vehicle that is organized as a Bermuda limited partnership, which corresponds to each class of WMIB securities. Each Offshore Fund invests primarily in publicly-traded securities, although up to 15% of each Offshore Fund may be invested in securities that are not readily marketable.

(f) The term ''U.S. broker-dealer'' means a broker-dealer registered in the United States under the Securities Exchange Act of 1934 (the 1934 Act) or exempted from registration under section 15(a)(1) of the 1934 Act as a dealer in exempted government securities (as defined in section 3(a)(12) of the 1934 Act).

(g) The term ''foreign broker-dealer'' means a broker that has, as of the last day of its most recent fiscal year, equity capital that is the equivalent of not less than $200 million and is registered and regulated, under the relevant securities laws of a governmental entity of a country other than the United States, where such regulation and oversight by the governmental entities is comparable to regulatory regimes within the United States.

(h) ''Manager Shares'' refer to the equity securities of an Offshore Corporation that have voting rights and control the election of the Board of Directors of an Offshore Corporation. Manager Shares do not participate in the economic performance of the Offshore Corporation and are owned 100% by Wellington Global Administrator.

(i) ''Shares'' refer to the equity securities of an Offshore Corporation that do not have voting rights. Such shares represent substantially all of the economic value of the Offshore Corporation and are or will be directly linked either (i) by class to a corresponding Offshore Fund (in the case of WMIB) or (ii) to a mix of various WMIB classes (in the case of Archipelago or any other fund of funds entity).

Effective Date: If granted, this proposed exemption will be effective retroactively for the transactions involving Wellington and two Client Plans that occurred from January 1, 2001 until December 31, 2003. For prospective transactions involving Wellington and a Client Plan, this proposed exemption will be effective on the date the notice granting the final exemption is published in the **Federal Register**.

Summary of Facts and Representations

1. Wellington, or the applicant (the Applicant), is a Massachusetts limited liability partnership that is a federally registered investment adviser and a financial services organization. Wellington manages the assets of many individual and institutional clients. As of September 30, 2006, Wellington had over $544 billion in assets under management, including the assets of many ERISA-covered employee benefit plans.

2. Wellington currently sponsors two offshore, open-end limited liability investment companies (i.e., the Offshore Corporations)—Wellington Management Investors (Bermuda), Ltd. (WMIB) and Archipelago Holdings, Ltd. (Archipelago). Each Offshore Corporation was formed under the laws

of Bermuda. WMIB, which is a conduit vehicle and does not have an investment manager, is structured in a manner that is similar to a ''series fund.'' It presently has outstanding nine classes of equity interests, each of which is linked to a separate collective investment vehicle that is organized as a Bermuda limited partnership (i.e., the Offshore Funds). There is a separate Bermuda limited partnership that corresponds to each class of WMIB securities.[2] All amounts distributed to WMIB by a particular Offshore Fund are distributed to the holders of the corresponding class of WMIB securities. Each Offshore Fund invests primarily in publicly-traded securities, although up to 15% of such fund may be invested in securities that are not readily marketable.

Wellington Management Investment, a Delaware corporation, which is wholly owned by Wellington Management, does not have any contractual relationship with, or provide any services to, the Offshore Corporations or the Offshore Funds. Wellington Management Investment holds a 0.025% interest in Wellington Global Holdings, a 0.1% interest in Wellington Global Administrator and a 0.1% interest in Wellington Hedge Management. The remaining interests in each such entity are directly held by Wellington Management, so that all three entities are nearly 100% owned by Wellington Management.

Wellington Global Holdings serves as the investment general partner of each WMIB Offshore Fund and, in such capacity, has hired Wellington Management as the investment sub-adviser of each WMIB Offshore Fund. Wellington Global Holdings also serves as the investment manager of Archipelago. Wellington Global Administrator serves as the administrative general partner of each WMIB Offshore Fund and also as the administrative manager of Archipelago. Wellington Hedge Management serves as the general partner of the Wellington-sponsored domestic ''onshore'' hedge funds, but has no responsibility or relationship with respect to the Offshore Corporations or the Offshore Funds.

In the future, WMIB may be expanded by Wellington to include additional classes of equity interests and additional Offshore Funds, corresponding in each case to the new WMIB class of equity interest. The future classes of equity interests and Offshore Funds will be established pursuant to the WMIB structure.

3. Archipelago is a ''fund of funds'' in that all of its assets are invested in a mix of the WMIB classes and, as a result, indirectly in a mix of the Offshore Funds and other funds associated with those particular classes[3]. Archipelago operates as a conduit vehicle as well (in that the investments made by Archipelago (i.e., the WMIB asset classes) are, in most instances, pre-specified as are the specific percentages to be invested in each such class). Wellington Global Holdings serves as investment manager to Archipelago and has limited discretionary authority in that capacity.[4]

4. The Applicant explains that a Client Plan may choose to invest in Archipelago, rather than directly in the various classes of WMIB shares, because the amount it is investing may be too small to enable it to achieve the degree of diversification it desires among the various Offshore Funds. In particular, the WMIB classes typically require a minimum investment of $1–$3 million per class. For a relatively small investment (Archipelago's minimum investment is approximately $1 million), Archipelago represents an opportunity for greater diversification according to the Applicant.[5] On an annual basis, Archipelago automatically rebalances its investments in the underlying WMIB classes to maintain the pre-specified target allocations.

Wellington represents that it may in the future establish additional Offshore Corporations that are substantially similar to Archipelago. However, these future ''fund of funds'' investment vehicles will invest in a different mix of WMIB classes than Archipelago.

5. The Applicant explains that within the universe of hedge funds, WMIB and Archipelago are not considered highly leveraged, nor will any future Offshore Corporations be highly leveraged. The Applicant states that many other hedge funds are more highly leveraged than WMIB and Archipelago. The Applicant bases this opinion on the SEC's Staff Report, ''Implications of the Growth of Hedge Funds'' (September 2003), which noted that, if a leverage ratio is defined as the ratio of total absolute dollars invested to total dollars of equity, a leverage ratio of greater than 2 to 1 is considered ''high'' while a ratio of less than or equal to 2 to 1 is considered ''low.'' When applying this criterion to the Offshore Funds, the Applicant states that historically, in most instances, total leverage exposure of each Offshore Fund has been substantially less than 2 to 1, and is consistent with the SEC's view that the leverage ratio is low.

Further, each Offshore Corporation margins its long securities only through its prime broker, which is subject to the terms of Regulation T issued by the Board of Governors of the Federal Reserve System pursuant to the Securities Exchange Act of 1934. The Offshore Corporations are limited to 100% leverage with respect to long securities,[6] they may short sell

[2] WMIB actually has 11 classes of equity interests. However, two of these classes relate to funds that have different characteristics than those described herein, and such classes are not intended to be covered by this exemption. Therefore, the existence of these two classes (and the corresponding Offshore Funds) should be disregarded in this proposed exemption except for the fact that interests in these two classes are held by Archipelago.

[3] Archipelago initially invested in six WMIB classes. Over time, however, two of these original six WMIB classes have been closed to new investment by Archipelago and two different WMIB classes have been substituted for new investments. Although new investments into Archipelago are allocated among six WMIB classes, Archipelago's assets are still invested in eight WMIB classes. Two of these eight WMIB classes, including one to which new Archipelago investments are allocated, correspond with underlying Bermuda limited partnerships that are not ''Offshore Funds,'' as defined in this proposed exemption, due to the fact that each such limited partnership permits investment in illiquid private placements that are not readily marketable to exceed 15% and has certain restrictions on redemptions. Because these two WMIB classes are not Offshore Funds, as defined in this proposed exemption, no plans will be permitted to invest in these WMIB classes.

[4] For example, Wellington Global Holdings oversees annual rebalancings of the underlying WMIB classes held by Archipelago. In addition, Wellington Global Holdings may determine to direct Archipelago investments in different percentages among the six current WMIB classes or to different WMIB classes. However, in either event, notice of the proposed change would be given to all affected investors in advance of such change.

[5] The minimum investment can be waived by Wellington.

[6] The Applicant states that the reference to ''100% leverage'' with respect to its long securities is not inconsistent with its representation that the Offshore Funds are not highly leveraged. For one thing, the Applicant represents that this statement relates only to the limit imposed by Regulation T on an investor's ability to invest on margin (i.e., with funds borrowed from the relevant broker). The Applicant states that in fact, the Offshore Funds do not come close to approaching this limit. The Applicant further states that Regulation T would permit a maximum long exposure percentage of 200% (i.e. 100% leverage), whereas the long exposure number for the WMIB and Archipelago class funds never exceeds 150%.

In addition, the Applicant states that ''100% leverage'' with respect to its long securities'' means that the Offshore Fund could utilize $100 of its own capital to purchase long securities and an additional $100 of borrowed funds to purchase long securities yielding a total long security position of $200 of which 50% would be attributable to debt and 50% would be attributable to the investment of its own equity. This would be analogous to an investment in real estate in which a property is bought for $200 with a mortgage of $100 with the remaining $100 being derived from the investor's own capital.

Moreover, the Applicant explains that since a Plan is likely to invest a small percentage of its assets in any particular Offshore Fund it may well be completely prudent and appropriate for some plan assets to be invested in an Offshore Fund that

securities, and may engage in derivative transactions. The derivative transactions are tracked daily and are not a significant source of leverage.

Moreover, the Applicant states that the Offshore Corporations are designed to provide absolute returns rather than to outperform a designated market.[7] Therefore, the Offshore Corporations do not utilize tracking errors as risk management tools.

6. Each Offshore Corporation has (or will have) two broad classes of equity securities—Manager Shares and Shares. Manager Shares are voting shares and hence control the election of the Board of Directors of an Offshore Corporation, but do not participate in the economic performance of the Offshore Corporation. Manager Shares are owned 100% by Wellington Global Administrator. Shares are non-voting but represent substantially all of the economic value of the Offshore Corporation and are or will be directly linked either (a) by class to a corresponding Offshore Fund (in the case of WMIB) or (b) to a mix of various WMIB classes (in the case of Archipelago or any other fund of funds entity). Shares are presently owned by numerous investors, primarily unrelated non-U.S. individuals and institutions and unrelated U.S. non-taxable investors, but not by any Client Plans.

In order to comply with National Association of Securities Dealers (NASD) rules (the ''new issues rules'') relating to the allocation of certain initial public offerings (IPOs), each Offshore Corporation offers three sub-classes of Shares: A Shares, which participate fully in initial public offering (IPO) allocations; C Shares, which participate only to a limited extent (i.e., only to the extent permitted by the applicable NASD rules) in IPO allocations; and E Shares, which do not participate to any extent in IPO allocations. In all other respects, these three sub-classes are identical. These NASD rules only impact investors that are professional money managers or broker-dealers as well as certain of their respective affiliates and related persons. All other investors would be required to invest in A Shares.[8]

Client Plans that are not ''restricted'' (as defined in NASD Rule 2790[9]) would acquire Class A shares. Client Plans that are restricted would acquire Class C shares. Only Client Plans that are sponsored solely by a broker-dealer would be deemed to be ''restricted.''

In addition, each Share sub-class is further divided into a different series in order to account for different loss carryforwards associated with specific Shares held by investors depending upon their holding periods with respect to such Shares. According to the Applicant, the separate accounting and the resultant separate series are needed in order to reflect the correct incentive allocation amounts with respect to each investor. In this regard, the incentive allocation payable to Wellington Global Holdings, as the investment general partner, at the Offshore Fund level incorporates a ''high-water mark''[10] concept. Application of that concept requires that investments made at different times be accounted for separately. The various series provide a mechanism for such separate accounting.

7. Each Offshore Corporation is exempt from registration under the Investment Company Act of 1940 (the 1940 Act) by reason of Section 3(c)(7) of the 1940 Act (i.e., all U.S. investors in the Offshore Corporation must be ''qualified purchasers''). In addition, the assets of each Offshore Corporation are not currently, and are not expected to be, ''plan assets'' subject to the Act because the aggregate interests of each class of equity securities issued by the Offshore Corporation that are held by ''benefit plan investors'' are currently, and are expected to be, less than 25% of the aggregate outstanding interests of such class (determined in accordance with the plan assets regulation).[11]

8. As an investment adviser registered under the Investment Advisers Act of 1940, Wellington Management is subject to the jurisdiction of the SEC. In this respect, the Applicant states that Wellington Management is subject to regulatory review and oversight by the SEC, which review encompasses all of Wellington Management's client relationships, including its relationships with the Offshore Corporations and the Offshore Funds. The sub-advisory agreement pursuant to which Wellington Management manages the assets of each Offshore Fund provides that such agreement is subject to the laws of Massachusetts (to the extent not preempted by applicable U.S. federal law). As a resident of Massachusetts, Wellington Management is subject to the jurisdiction of the state and federal courts in Massachusetts. Moreover, each Offshore Corporation, each Offshore Fund, Wellington Global Holdings and Wellington Global Administrator, will consent to the jurisdiction of such courts, and will appoint Wellington Management as its agent for service of process.

9. Wellington's compensation is paid exclusively at the Offshore Fund-level. Thus, Wellington will receive no duplicate fees from a Client Plan. In this

is more highly leveraged and therefore more risky, when such investment is viewed in the context of the Plan's overall portfolio and the other relevant facts and circumstances applicable to the particular plan that would affect its appetite for risk. The Applicant believes these are factors that must be taken into account by the independent Plan fiduciary prior to investing in a particular Offshore Fund.

[7] Absolute return strategies are designed to move independently of the underlying markets and have lower correlations to the broader markets. During falling markets, the performance of a fund should stay independent from that of broader market movements, thus providing protection from those downward movements. In rising markets, funds employing absolute return strategies lag behind more traditional long-only investments. See ''Implications of the Growth of Hedge Funds,'' at 111.

[8] WMIB also offers S Shares with respect to classes that invest in underlying funds that are not intended to be covered by this exemption, except to the extent of Archipelago's interest therein.

[9] On October 24, 2003, the SEC approved new Rule 2790 (Restrictions on the purchase and sale of IPOs of equity securities), which replaces the Free-Riding and Withholding Interpretation (IM–2110–1). Rule 2790 prohibits a NASD member from selling a ''new issue'' to any account in which a ''restricted person'' has a beneficial interest. The term ''restricted person'' includes most associated persons of a member, most owners and affiliates of a broker-dealer, and certain other classes of persons. The Rule requires that a member, before selling a new issue to any account, meet certain ''preconditions for sale,'' which require the member to obtain a representation from the beneficial owner of the account that the account is eligible to purchase new issues in accordance with the Rule. The Rule also contains a series of general exemptions.

[10] The Applicant states that Wellington Global Holdings is entitled to an incentive allocation equal to a specified percentage (typically 20 percent) of the net profits during each fiscal year. However, the Applicant notes that if there is a loss in any fiscal year, then no incentive allocation will be made with respect to subsequent net profits allocable to shareholders who incurred the loss until the cumulative net loss has been fully offset by subsequent net profits allocable to such shareholders. The Applicant states that although this structure is often referred to as a high-water mark, it may be easier to understand as a loss carryforward.

[11] The Applicant states that its current intention is to keep investments by Client Plans, or ''benefit plan investors'' (as defined by section 3(42) of the Act), in each class of the Offshore Corporations' Shares below 25% and thereby avoid plan asset status. The Applicant represents that it monitors the level of investment by Client Plans each time there is any cash flow to make sure that the Offshore Corporations remain below the 25% threshold in each class. To the extent necessary, the Applicant explains that it may mandatorily redeem a Client Plan's Shares if necessary to remain below 25%. However, in the event benefit plan investors are allowed to exceed the 25% threshold and the underlying assets of the affected Offshore Corporations become plan assets, the Applicant states that it would comply with the applicable fiduciary obligations under the Act during any period that the assets being managed by Wellington include any plan assets. Under such circumstances, the Applicant states that it would provide advance notice to all investors in the affected entity and would not allow the 25% threshold to be exceeded until all such investors had an opportunity to redeem their Shares should they desire not to continue to invest in a plan assets vehicle.

regard, each Offshore Fund pays Wellington an aggregate annual management fee equal to one percent of the Offshore Fund's net assets. The management fee is paid quarterly in arrears and is calculated based on the value of the net assets of the Offshore Fund at the end of the quarter. Also, as discussed in Representation 6 and the footnote reference with respect thereto, each Offshore Fund allocates 20 percent of its net profits to Wellington Global Holdings on an annual basis or upon a full redemption by a Client Plan. There are no additional management fees incurred at the Offshore Corporation level.[12]

Wellington believes its compensation with respect to these entities is reasonable, within the meaning of section 408(b)(2) of the Act and the regulations promulgated thereunder, and consistent with (and in many cases lower than) the levels of compensation charged by other managers of comparable entities. In addition, Wellington states that the reasonableness of its compensation is further evidenced by the fact that substantially all of the investors in these entities are independent of Wellington and all investors have made their decisions to invest in such entities after full disclosure of the level of compensation to be charged.

10. The Applicant believes that certain of its clients may desire to invest in one or more Offshore Corporations. In particular, U.S. tax-exempt investors, including Client Plans, frequently invest in offshore funds structured as corporations (for U.S. tax purposes) in order to minimize the amount of unrelated business taxable income they incur as a result of certain investment strategies and activities. In effect, the Applicant states that the introduction of the Offshore Corporation shields the Client Plan from any unrelated business taxable income, thereby enhancing the after-tax investment return of the Client Plan. Because an investment in an Offshore Corporation would allow Client Plans to invest in these investment strategies and activities on the most tax efficient basis, the Applicant believes that it is in the best interest of Client Plans and their participants and beneficiaries, and also consistent with the requirements of section 408(a) of the Act, for the Department to grant an administrative exemption for the past and future acquisition and redemption of an Offshore Corporation's non-voting Shares by a Client Plan.

11. Accordingly, the Applicant requests an administrative exemption from the Department that would permit a Client Plan to acquire Shares from an Offshore Corporation. The exemption would also allow the Client Plan to redeem Shares from an Offshore Corporation, either in cash or in kind. An administrative exemption is required because Wellington Management is (or may become) a party in interest with respect to a Client Plan, as a fiduciary and a service provider under section 3(14)(A) and (B) of the Act. Wellington Management would also be considered a party in interest with respect to a Client Plan under section 3(14)(H) of Act because it owns directly 10% or more of Wellington Global Administrator, a service provider to a Client Plan. In this respect, Wellington Management owns more than 99% of the common stock of Wellington Global Administrator and indirectly, more than 99% of Manager Shares.

In addition, Wellington Global Administrator is a party in interest with respect to a Client Plan under section 3(14)(H) of the Act inasmuch as it is a 10% or more shareholder of an Offshore Corporation due to its ownership of 100% of Manager Shares.

Further, an Offshore Corporation would be considered a party in interest with respect to a Client Plan because under section 3(14)(G) of the Act, it is a corporation in which 50% of the combined voting power of all stock entitled to vote is owned directly by Wellington Global Administrator, a service provider, and indirectly by Wellington Management, a fiduciary and a service provider.

Therefore in the absence of an administrative exemption, the acquisition or redemption by a Client Plan of Shares from an Offshore Corporation would constitute a prohibited purchase and sale transaction between the Client Plan and a party in interest in violation of section 406(a)(1)(A) and (D) of the Act.

Because all decisions with respect to a Client Plan's acquisition or redemption of Shares would be (or have been made) by independent fiduciaries of Client Plans which are unrelated to Wellington, no exemption from section 406(b) of the Act is being requested by the Applicant.

If granted, the exemption would provide retroactive relief, effective from January 1, 2001 until December 31, 2003 for transactions involving two Client Plans that formerly invested in the Offshore Corporations. The exemption would also provide prospective relief that would be effective on the date the grant notice is published in the **Federal Register** for future investments by Client Plans in the Offshore Corporations.

The Applicant is aware that the prospective transactions described herein may be covered by the statutory exemption for service providers under section 408(b)(17) of the Act. Section 408(b)(17) of the Act requires that, in connection with transactions entered into pursuant to this statutory exemption, that a plan receive no less nor pay no more than ''adequate consideration.'' For purposes of the statutory exemption, the term ''adequate consideration'' means,

- In the case of a security for which there is a generally recognized market—
  - The price of the security prevailing on a national securities exchange which is registered under section 6 of the Securities Exchange Act of 1934, taking into account factors such as the size of the transaction and marketability of the security, or
  - If the security is not traded on a national securities exchange, a price not less favorable to the plan than the offering price for the security established by the current bid and asked prices quoted by persons independent of the issuer and of the party in interest, taking into account factors such as the size of the transaction and marketability of the security, and
- In the case of an asset other than a security for which there is a generally recognized market, the fair market value of the asset as determined in good faith by a fiduciary or fiduciaries in accordance with regulations prescribed by the Secretary of Labor.

The Applicant is concerned about the requirement in section 408(b)(17) that the plan ''receives no less, nor pays no more, than adequate consideration.'' In this context, the Applicant explains that this provision means fair market value as determined in good faith by the relevant plan fiduciary in accordance with regulations prescribed by the Department. In the absence of such regulations, the Applicant states that the determination of what constitutes adequate consideration is unclear, particularly if the underlying assets of an Offshore Fund are invested in securities and other investments that are not publicly-traded. But for this concern, the Applicant states that the statutory relief provided under section 408(b)(17) of the Act would be adequate for prospective transactions.

12. The Applicant requests retroactive exemptive relief with respect to the

[12] Although the Applicant reserves the right to change its fee in the future, it states that in all cases, any such change would be fully disclosed to investors in advance. Any existing investors would then have an opportunity to withdraw from the affected Offshore Fund before the fee change became effective without penalty.

investment by two Client Plans in an Offshore Corporation. Specifically, the NCR Pension Plan (the NCR Plan) and the Lahey Clinic Pension Plan (the Lahey Plan) inadvertently acquired interests in an Offshore Corporation in January 1, 2001 and July 1, 2003, respectively. The NCR Plan invested $27,200,000 in the WMIB Offshore Corporation on January 1, 2001 in order to acquire Class A Shares. Based upon an available Form 5500, the NCR Plan had total assets of approximately $3 billion on December 31, 2000. Therefore, the NCR Plan's investment in WMIB represented approximately 1% of that Client Plan's assets. In addition, WMIB made no interim distributions to the NCR Plan during the Client Plan's ownership of Shares. On December 31, 2003, the NCR Plan redeemed its interest in WMIB partially in cash and partially in kind. As the redemption amount, the NCR Plan received $31,052,990.

The Lahey Plan invested $6 million in Archipelago on July 1, 2003 to acquire Class A Shares. Based upon an available Form 5500, the Lahey Plan had total assets of approximately $150 million as of September 30, 2003. Thus, the Lahey Plan's investment in Archipelago represented approximately 4% of that Client Plan's assets. During its ownership of the Class A Shares, Archipelago made no interim distributions to the Lahey Plan. On December 31, 2003, the Lahey Plan redeemed its interest in Archipelago in cash. The Lahey Plan received $6,712,168.

It is represented that Wellington did not provide investment advice (within the meaning of 29 CFR 2510.3–21(c)), nor was it a fiduciary, with respect to either the Lahey Plan's or the NCR Plan's investments in the Class A Shares. Rather, in each case, the decision to acquire Class A Shares was made by an authorized fiduciary of the Client Plan who was independent of Wellington. Neither the independent fiduciary of the Client Plan nor Wellington had any knowledge that such acquisition would give rise to a prohibited transaction under section 406(a) of the Act. This was because the parties were not aware that Wellington Management's 95% indirect ownership of Manager Shares in WMIB and Archipelago resulted in either Offshore Corporation becoming a party in interest with respect to the applicable Client Plan. When the prohibited transaction concern was identified, the Applicant states that each Client Plan redeemed its interest in the Offshore Corporation in December 2003, within a reasonable period of time after such discovery. In the case of the Lahey Plan, the redemption was made entirely in cash, while the NCR Plan requested, and was given, a redemption that was partially in cash and partially in kind. The NCR Plan was permitted to receive an in-kind redemption in part because it intended to reinvest its redemption proceeds in a parallel domestic fund, also managed by Wellington.[13] In view of this intent, the Applicant believes that it was more efficient and cost effective (i.e., by avoiding transaction costs) to effect a partial redemption in kind. Neither Client Plan incurred a loss as a result of its investment in the Offshore Corporation.

During their investment in the Offshore Corporations, both the Lahey Plan and the NCR Plan were provided with the opportunity to access, among other things, monthly unaudited performance reports and audited annual financial statements. Both the Lahey Plan and the NCR Plan were also able to access this information online or through paper mailings that were initially given to the sponsor of the NCR Plan. In addition, during the entire duration of their respective investments, both Client Plans had telephone access to the Wellington's Hedge Fund Group for assistance with any questions they may have had.

Neither the NCR Plan nor the Lahey Plan paid any sales or redemption fees or commissions in connection with their subscription and redemption of Class A Shares. Like all other investors, the Client Plans did indirectly bear the management fee and incentive allocation borne by the underlying partnerships to which their respective Class A Shares related.

13. With respect to the determination of fair market value for purposes of the redemption transactions relating to the NCR Plan and the Lahey Plan, the Applicant states that to the extent that any of the assets of an Offshore Fund consisted of publicly-traded securities or other assets for which independent market prices were available, the public market prices or independent pricing sources were utilized. The Applicant further states that to the extent that any of the assets of an Offshore Fund were not capable of being valued in this manner, Wellington Management's pricing committee, which is comprised of senior Wellington investment professionals, determined the fair value of such assets pursuant to its Fair Value Pricing Practices.[14] Wellington contemplates that not more than 5% of the securities held by an Offshore Fund which are not readily marketable will be subject to its Fair Value Pricing Practices.

14. Given that (a) there was no awareness of the technical prohibited transaction concern involved, (b) the investment decision was made by an independent fiduciary on the same terms as all other investors in the Offshore Corporation after receipt of an offering memorandum describing the details of the investment, (c) each of these two Client Plans had, at the time of investment, aggregate assets in excess of $100 million, (d) each Client Plan redeemed its entire interest in the Offshore Corporation within a reasonable period of time after the prohibited transaction concern was discovered, and (e) neither Client Plan incurred a loss on account of its investment in the Offshore Corporation, the Applicant believes that a retroactive exemption covering the acquisition and redemption of interests in the Offshore Corporations by these two Client Plans is appropriate. For these Client Plans, the exemption would be effective

[13] The Applicant states that the redemption proceeds received by the NCR Plan were invested in Quisset Partners, L.P. (the Domestic Fund), a private investment fund organized as a Delaware limited partnership that is sponsored and managed by Wellington in a substantially similar manner to the Offshore Fund from which the NCR Plan was redeemed. The Applicant further states that the decision to invest in the Domestic Fund was made by an independent fiduciary of the NCR Plan without any fiduciary involvement by Wellington or any of its affiliates. The Applicant confirms that the assets of the Domestic Fund are not plan assets subject to the Act due to the fact that the holdings of equity interests in the Domestic Fund are such that ownership by benefit plan investors is not significant within the meaning of section 3(42) of the Act. Nevertheless, the Department is not proposing, nor is the Applicant requesting, exemptive relief with respect to the NCR Plan's investment in the Domestic Fund.

[14] The Applicant states that a fair value pricing determination is intended to provide, on a best-efforts basis, the price at which the security could reasonably be expected to be sold in an arm's length transaction. The Applicant notes that a fair value determination does not contemplate the price at which the entire position would be sold; each situation is appraised individually and only a small percentage (typically in the range from 0–5%) of its holdings will be subject to fair value pricing at any one time. The Applicant considers the following factors in determining whether fair valuation is required: (a) Prices are unavailable on an exchange or market; (b) prices are unavailable from brokers/market makers; (c) a determination that prices from vendor/broker sources are stale or incorrect; (d) a private placement investment; (e) notice of default or the initiation of bankruptcy proceedings; (f) a determination that an investment has become worthless; (g) certain corporate reorganizations; (h) a ''significant event'' has occurred with respect to a security or market.

In making its fair value pricing determination, the Applicant represents that it utilizes a set of defined decision rules, which involve varying degrees of objectivity, an independent review process, and a continuing review of securities in fair value status. The valuation process is operated in a consistent manner over time as well as among investor accounts.

between January 1, 2001 and December 31, 2003.

15. The Applicant represents that the following safeguards for the prospective exemption will be in place:

• All decisions to acquire or redeem Shares will be made or are made on behalf of the Client Plan by an independent fiduciary.

• The Client Plan, either individually or through a pooled investment vehicle such as a master trust or a pooled fund, will have assets at least equal to $100 million. For example: (a) In the case of a master trust that holds assets of multiple related Client Plans maintained by a single employer or a controlled group of employers, as defined by section 407(d)(7) of the Act, this requirement will be satisfied if the master trust has aggregate assets at least equal to $100 million (assuming the fiduciary responsible for making the investment decision is the Client Plan sponsor or an affiliate of the Client Plan sponsor); or (b) in the case of a pooled fund (e.g., a group trust) whose assets are ''plan assets'' subject to the Act, this requirement will be satisfied as long as either (1) the pooled fund has at least $100 million in aggregate assets and the fiduciary making the investment decision is unrelated to Wellington and manages at least $200 million in assets (exclusive of the aggregate assets invested in the Offshore Corporations); or (2) at least 50 percent of the units of beneficial interest in the pooled fund are held by Client Plans, each of which has total net assets of at least $100 million.

• Wellington will not provide investment advice (within the meaning of 29 CFR 2510.3–21(c)), nor is it a fiduciary with respect to any Client Plan investment in an Offshore Fund.

• All acquisitions and redemptions of Shares by a Client Plan will be for fair market value, determined as follows: (a) equity securities will be valued at their last sale price or official closing price on the market on which such securities primarily trade using sources independent of Wellington and the issuer. If no sales occurred on such day, equity securities are valued at the last reported independent ''bid'' price or, if sold short, at the last reported independent ''asked'' price; (b) fixed income securities will be valued either on the basis of ''firm quotes'' obtained at the time of the acquisition or redemption of Shares from U.S.-registered or foreign broker-dealers, which are registered and subject to the laws of their respective jurisdiction, which quotes reflect the share volume involved in the transaction, or on the basis of prices provided by independent pricing services that determine valuations based on market transactions for comparable securities and various relationships between such securities that are generally recognized by institutional traders; (c) options will be valued at the mean between the current independent ''bid'' price and the current independent ''asked'' price or, where such prices are not available are valued at their fair value in accordance with Fair Value Pricing Practices by Wellington Management's pricing committee, which utilizes a set of defined rules and an independent review process; or (d) if current market quotations are not readily available for any investments, such investments will be valued at their fair value by Wellington Management's pricing committee, in accordance with Fair Value Pricing Practices.

• A Client Plan's Shares will be redeemed, in whole or in part, without the payment of any redemption fee or other penalty, on a pre-specified, periodic (not longer than semi-annual) basis, upon no more than 45 days' advance notice, except for a one-year lock-up period imposed on new investors. (If the Applicant extends the lock-up period to existing investors, such investors would receive advance notice and have an opportunity to withdraw from the affected Offshore Fund without penalty before the change become effective.)

• Redemptions of Shares in an Offshore Corporation by a Client Plan will be made in cash unless: (a) A Client Plan consents to such in kind redemption; or (b) Wellington requires that such redemption be made in kind on a pro rata basis to protect the best interests of the Offshore Fund and the remaining investors, including other Client Plan investors. (Each Offshore Corporation may redeem Shares in kind if deemed by the Board of Directors to be in the best interests of the Offshore Corporation. There is no threshold over which redemptions are automatically funded in kind, nor is there any minimum amount of redemption below which the redemption cannot be made in kind.)

• In advance of the initial investment by a Client Plan in an Offshore Corporation's Shares, the relevant independent fiduciary will receive: (a) A copy of the proposed and final exemption for prospective relief described herein; (b) an offering memorandum describing the relevant Offshore Fund(s), as well as the relevant investment objectives, fees and expenses and redemption and valuation procedures; and (c) all reasonably available relevant information as such independent fiduciary may request.

• On an ongoing basis, Wellington will provide a Client Plan with the following information: (a) Unaudited performance reports at the end of each month; (b) audited annual financial statements and access to a protected internet site; and (c) client services group assistance for any investor inquiries.

• No commission or sales charge will be assessed against the Client Plan in connection with its acquisition of an Offshore Corporation's Shares.

• Not more than 10% of the assets of the Client Plan will be invested, in the aggregate, in non-voting Shares of all Offshore Corporations (determined at the time of any acquisition of the Shares) and not more than 5% of the assets of the Client Plan will be invested, in the aggregate, in any one Offshore Fund (determined at the time of any acquisition of an interest in such Offshore Fund by such Client Plan).

• Each Offshore Corporation, each Offshore Fund, Wellington Management Investment, Wellington Global Holdings, Wellington Hedge Management, and Wellington Global Administrator will consent to the jurisdiction of the federal and state courts located in the Commonwealth of Massachusetts and has appointed Wellington Management as its agent for service of process.

• Wellington will maintain in the United States for a period of six years from the date of the covered transactions, such records as are necessary to enable any duly authorized employee or representative of the Department or the Service, any fiduciary of a Client Plan, or any participant or beneficiary of a Client Plan to determine whether the conditions of this exemption have been or are met.

16. In summary, the Applicant represents that the transactions have satisfied or will satisfy the statutory criteria for an exemption under section 408(a) of the Act because:

(a) All decisions to acquire or redeem such Shares have been or will be made on behalf of the Client Plan by an authorized fiduciary who is independent of Wellington and the applicable Offshore Corporation;

(b) At the time of acquisition of Shares from an Offshore Corporation, each Client Plan has had or will have assets at least equal to $100 million either individually or through a pooled arrangement.

(c) Wellington has not provided or will not provide investment advice (within the meaning of 29 CFR 2510.3–21(c)), nor is it a fiduciary with respect

to any Client Plan's investment in an Offshore Fund.

(d) A Client Plan's Shares have been redeemed or will be redeemed, in whole or in part, without the payment of any redemption fee or other penalty, on a pre-specified, periodic (not longer than semi-annual) basis, upon no more than 45 days' advance notice, except for a one-year lock-up period imposed on new investors.

(e) All acquisitions and redemptions of Shares by a Client Plan have been made or will be made for fair market value or have been valued or will be valued by Wellington Management's pricing committee, which utilizes a set of defined rules and an independent review process, all in accordance with Fair Value Pricing Practices.

(f) Redemptions of interests in an Offshore Corporation by a Client Plan have been made or will be made in kind or cash unless: (1) A Client Plan consents to such in kind redemption; or (2) Wellington requires that such redemption be made in kind to protect the best interests of the Offshore Fund and the remaining investors, including other Client Plan investors.

(g) In advance of the initial investment by a Client Plan in an Offshore Corporation's Shares, the relevant independent fiduciary has received or will receive: (1) A copy of the proposed exemption and the final exemption (This disclosure provision applies to the prospective exemptive relief described herein.); (2) an offering memorandum describing the relevant Offshore Fund(s), as well as the relevant investment objectives, fees and expenses and redemption and valuation procedures; and (3) all reasonably available relevant information as such independent fiduciary may request.

(h) On an ongoing basis, Wellington has provided or will provide the independent fiduciary of a Client Plan with the following information: (1) Unaudited performance reports at the end of each month; (2) audited annual financial statements and access to a protected internet site; and (3) client services group assistance for any investor inquiries.

(i) No commission or sales charge has been assessed or will be assessed against the Client Plan in connection with its acquisition of an Offshore Corporation's Shares.

(j) Not more than 10% of the assets of the Client Plan has been invested or will be invested, in the aggregate, in non-voting Shares of all Offshore Corporations (determined at the time of any acquisition of such Shares) and not more than 5% of the assets of the Client Plan has been indirectly invested or will be invested, in the aggregate, in any one Offshore Fund (determined at the time of any acquisition of an interest in such Offshore Fund by such Client Plan).

(k) For prospective transactions only, each Offshore Corporation, each Offshore Fund, Wellington Management Investment, Wellington Global Holdings, Wellington Hedge Management, and Wellington Global Administrator will consent to the jurisdiction of the federal and state courts located in the Commonwealth of Massachusetts and has appointed Wellington Management as its agent for service of process.

(l) For prospective transactions only, Wellington will maintain in the United States for a period of six years from the date of the covered transactions, such records as are necessary to enable such persons as any duly authorized employee or representative of the Department or the Service, any fiduciary of a Client Plan, or any participant or beneficiary of a Client Plan, to determine whether the conditions of this exemption will be met.

17. The Department notes that the general standards of fiduciary conduct under the Act would apply to the transactions permitted herein, and that the satisfaction of the conditions of this exemption should not be viewed as an endorsement, by the Department, of investments in the Offshore Corporations by Wellington's Client Plans. Therefore, the Department believes that it would be helpful to provide general information regarding its views on the responsibilities of an independent fiduciary of a Client Plan in connection with such plan's investment in an Offshore Corporation.

As noted in the Department's Interpretive Bulletin, 29 CFR 2509.94–3(d) (59 FR 66736, December 28, 1994), apart from consideration of the prohibited transaction provisions, a Client Plan's independent fiduciary must determine that such plan's investment in an Offshore Corporation is consistent with the general standards of fiduciary conduct under section 404 of the Act. In this regard, section 404(a)(1)(A) and (B) of the Act requires that fiduciaries discharge their duties to a plan solely in the interests of the participants and beneficiaries, for the exclusive purpose of providing benefits to participants and beneficiaries and defraying reasonable administrative expenses, and with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims. In addition, section 404(a)(1)(C) of the Act requires that fiduciaries diversify plan investments so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so.

Accordingly, the independent fiduciary of a Client Plan must act ''prudently,'' ''solely in the interest'' of the Client Plan's participants and beneficiaries, and with a view to the need to diversify such plan assets when deciding whether to invest plan assets in Shares of an Offshore Corporation. If such investment is not ''prudent,'' or not ''solely in the interest'' of the participants and beneficiaries of the plan or would result in an improper lack of diversification of plan assets, the responsible fiduciary or fiduciaries of the plan would be liable for any losses resulting from such a breach of fiduciary responsibility.

The Department further emphasizes that it expects the independent fiduciary to fully understand the benefits and risks associated with the Client Plan's investment in an Offshore Corporation, following disclosure to such fiduciary of all relevant information, including the fees that are paid to Wellington. Further, such plan fiduciary must be capable, either directly or indirectly through the use of hired professional experts, of monitoring the investment, including any changes in the performance of the investment. Thus, in considering a Client Plan's investment in an Offshore Corporation, an independent fiduciary should take into account its ability to provide adequate oversight of the particular investment.

FOR FURTHER INFORMATION CONTACT: Ms. Jan D. Broady of the Department, telephone number (202) 693–8556. (This is not a toll-free number.)

GE Asset Management Incorporated Located in Stamford, Connecticut

[Application No. D–11389]

Proposed Exemption

Section I—Exemption for In-Kind Redemption of Assets

The Department is considering granting an exemption under the authority of section 408(a) of the Act and 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR part 2570 subpart B (55 FR 32836, 32847, August 10, 1990). If the proposed exemption is granted, the restrictions in sections 406(a)(1)(A) through (D) and 406(b)(1) and (b)(2) of the Act, and the sanctions resulting from the application of section 4975 of the Code, by reason of section

4975(c)(1)(A) through (E) of the Code, shall not apply,[15] effective March 1, 2006, to certain in-kind redemptions (the Redemption(s)), by plans sponsored by the General Electric Company (GE) or an affiliate (the Plan(s)), of shares (the Shares) of certain proprietary mutual funds for which GE Asset Management Incorporated (GEAM) provides investment advisory and other services (the Mutual Fund(s)), provided that the following conditions are satisfied:

(A) The Plan pays no sales commissions, redemption fees, or other similar fees in connection with the Redemption (other than customary transfer charges paid to parties other than GEAM and any affiliates thereof (GEAM Affiliates));

(B) The assets transferred to the Plan pursuant to the Redemption consist entirely of cash and Transferable Securities, as such term is defined in Section II, below;

(C) With certain exceptions described below, the Plan receives in any Redemption its pro rata portion of the securities that, when added to the cash received, is equal in value to the number of Shares redeemed, as determined in a single valuation performed in the same manner and as of 4 p.m. (local time for the New York Stock Exchange) on the same day, in accordance with Rule 2a–4 under the Investment Company Act of 1940, as amended (the 1940 Act), and the then-existing procedures established by the Board of Trustees of the Mutual Fund (using sources independent of GEAM and GEAM Affiliates). Notwithstanding the foregoing, Transferable Securities that are odd lot securities, fractional shares, and accruals on such securities may be distributed in cash;

(D) Neither GEAM, nor any affiliate thereof, receives any direct or indirect compensation, or any fees, including any fees payable pursuant to Rule 12b–1 under the 1940 Act, in connection with any Redemption of the Shares;

(E) Prior to a Redemption, GEAM provides in writing to an independent fiduciary, as such term is defined in Section II (Independent Fiduciary), a full and detailed written disclosure of information regarding the Redemption;

(F) Prior to a Redemption, the Independent Fiduciary provides written authorization for such Redemption to GEAM, such authorization being terminable at any time prior to the date of Redemption without penalty to the Plan;

(G) Before authorizing a Redemption, based on the disclosures provided by GEAM to the Independent Fiduciary, the Independent Fiduciary determines that the terms of the Redemption are fair to the Plan, and comparable to, and no less favorable than, terms obtainable at arm's length between unaffiliated parties, and that the Redemption is in the best interests of the Plan and its participants and beneficiaries;

(H) Not later than thirty (30) business days after the completion of a Redemption, the Mutual Fund will provide to the Independent Fiduciary a written confirmation regarding such Redemption containing:

(i) The total number of Shares of the Mutual Fund and the percentage held by the Plan immediately before the Redemption (and the related per Share net asset value and the total dollar value of the Shares held);

(ii) The identity (and related aggregate dollar value) of each security provided to the Plan pursuant to the Redemption, including each security valued in accordance with Rule 2a–4 under the 1940 Act and the then-existing procedures established by the Board of Trustees of the Mutual Fund (using sources independent of GEAM and GEAM Affiliates);

(iii) The current market price of each security received by the Plan pursuant to the Redemption; and

(iv) The identity of each pricing service or market-maker consulted in determining the value of such securities;

(I) The value of the securities received by the Plan for each redeemed Share, when added to the cash received, equals the net asset value of such Share at the time of the transaction, and such value equals the value that would have been received by any other investor for shares of the same class of the Mutual Fund at that time;

(J) Subsequent to a Redemption, within 180 days of the date of such Redemption, the Independent Fiduciary performs a post-transaction review that will include, among other things, testing a sampling of material aspects of the Redemption deemed in its judgment to be representative, including pricing;

(K) Each of the Plan's dealings with the Mutual Funds, the investment advisers to the Mutual Funds, the principal underwriter for the Mutual Funds, or any affiliated person thereof, are on a basis no less favorable to the Plan than dealings between the Mutual Funds and other shareholders holding shares of the same class as the Shares;

(L) GEAM will maintain, or cause to be maintained, for a period of six years from the date of any covered transaction such records as are necessary to enable the persons described in paragraph (M) below to determine whether the conditions of this exemption, if granted, have been met, except that (i) this recordkeeping condition shall not be violated if, due to circumstances beyond the control of GEAM, the records are lost or destroyed prior to the end of the six year period, (ii) no party in interest with respect to the Plan other than GEAM shall be subject to the civil penalty that may be assessed under section 502(i) of the Act or to the taxes imposed by section 4975(a) and (b) of the Code, if such records are not maintained or are not available for examination as required by paragraph (M) below;

(M)(1) Except as provided in subparagraph (2) of this paragraph (M), and notwithstanding any provisions of section 504(a)(2) and (b) of the Act, the records referred to in paragraph (L) above are unconditionally available at their customary locations for examination during normal business hours by (i) any duly authorized employee or representative of the Department of Labor, the Internal Revenue Service, or the Securities and Exchange Commission (SEC), (ii) any fiduciary of the Plan or any duly authorized representative of such fiduciary, (iii) any participant, beneficiary, or union employee covered by the Plan or duly authorized representative of such participant, beneficiary, or union employee, (iv) any employer whose employees are covered by Plan and any employee organization whose members are covered by such Plan.

(2) None of the persons described in paragraphs (M)(1)(ii), (iii) and (iv) shall be authorized to examine trade secrets of GEAM or the Mutual Funds, or commercial or financial information that is privileged or confidential; and

(3) Should GEAM or the Mutual Funds refuse to disclose information on the basis that such information is exempt from disclosure pursuant to paragraph (2) above, GEAM shall, by the close of the thirtieth (30th) day following the request, provide a written notice advising that person of the reasons for the refusal and that the Department may request such information.

Section II—Definitions

(A) The term ''affiliate'' means:

(1) Any person (including a corporation or partnership) directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person;

[15] For purposes of this proposed exemption, references to specific provisions of Title I of the Act, unless otherwise specified, refer also to the corresponding provisions of the Code.

(2) Any officer, director, employee, relative, or partner in any such person; and

(3) Any corporation or partnership of which such person is an officer, director, partner, or employee.

(B) The term ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(C) The term ''net asset value'' means the amount for purposes of pricing all purchases and sales calculated by dividing the value of all securities, determined by a method as set forth in the Mutual Fund's prospectus and statement of additional information, and other assets belonging to the Mutual Fund, less the liabilities charged to each such Mutual Fund, by the number of outstanding shares.

(D) The term ''Independent Fiduciary'' means a fiduciary who is: (i) Independent of and unrelated to GEAM and its affiliates, and (ii) appointed to act on behalf of the Plan with respect to the in-kind transfer of assets from one or more Mutual Funds to, or for the benefit of, the Plan. For purposes of this proposed exemption, a fiduciary will not be deemed to be independent of and unrelated to GEAM if: (i) Such fiduciary directly or indirectly controls, is controlled by, or is under common control with GEAM, (ii) such fiduciary directly or indirectly receives any compensation or other consideration in connection with any transaction described in this proposed exemption (except that an independent fiduciary may receive compensation from GEAM in connection with the transactions contemplated herein if the amount or payment of such compensation is not contingent upon or in any way affected by the independent fiduciary's ultimate decision), and (iii) an amount equal to more than two percent (2%) of such fiduciary's gross income, for federal income tax purposes, in its prior tax year, will be paid to such fiduciary by GEAM and its affiliates in such fiduciary's current tax year.

(E) The term ''Transferable Securities'' means securities that are traded on public securities markets or for which quoted bid and asked prices are available from persons independent of GEAM and would not include the following types of securities or assets: (a) Securities that would have to be registered under the Securities Act of 1933, as amended; (b) securities issued by entities in countries that restrict the holdings of securities by non-nationals, including investment vehicles such as the Mutual Funds, or otherwise limit the ability to transfer the security other than through a local securities exchange transaction; and (c) certain portfolio assets (such as forward currency contracts, futures and option contracts, swap transactions, and repurchase agreements) that, although they may be liquid and marketable, involve the assumption of contractual obligations, require special trading facilities, or may be traded only with the counterparty to the transactions in order to effect a change in beneficial ownership.

(F) The term ''relative'' means a ''relative'' as such term is defined in section 3(15) of the Act (or a ''member of the family,'' as such term is defined in section 4975(e)(6) of the Code), or a brother, sister, or a spouse of a brother or a sister.

Summary of Facts and Representations

1. GE Asset Management Incorporated (i.e., GEAM) is a direct, wholly-owned subsidiary of the General Electric Company (i.e., GE). GEAM serves as investment adviser to the GE Funds, an open-end management investment company registered under the 1940 Act that consists of a number of series (the Retail Funds). The Retail Funds generally offer four classes of shares: A, B, C, and Y. Class Y shares are held by various institutional investors. Investors in Class Y shares of the Retail Funds do not pay sales commissions or redemption fees in connection with the purchase or redemption of such shares, nor do they pay any 12b–1 or similar fees with respect to the distribution of such shares. Individual account plans maintained by GE and its affiliates (i.e., the Plans), subject to the Act and the Code, were, in the past, invested in Class Y shares of certain Retail Funds.[16] The Retail Funds in which the Plans have in the past invested include the following: The International Equity Fund, U.S. Equity Fund, Strategic Investment Fund, Small-Cap Value Equity Fund, Premier Growth Equity Fund, Value Equity Fund, and Fixed Income Fund.

2. GEAM also serves as investment adviser to GE Institutional Funds, an open-end management investment company registered under the 1940 Act that consists of a number of portfolios (the Institutional Funds). The Institutional Funds are designed primarily for institutional investors, such as corporations, foundations, endowments, and trusts, as well as charitable, religious, and educational institutions. Shares of the Institutional Funds are currently offered in two classes: the Investment Class (Class I) and Service Class. Purchasers of Class I shares do not pay any sales charges (including front-end, contingent deferred, or asset-based sales charges), nor do they pay shareholder service and distribution fees in connection with their investments in the Institutional Funds.

The applicant represents that certain Institutional Funds have the same investment objectives, investment strategies, and portfolio managers as corresponding Retail Funds, and therefore have substantially identical portfolio holdings as those corresponding Retail Funds.[17] However, the expense ratios of the Institutional Funds are lower than the expense ratios of the corresponding Retail Funds. The Institutional Funds that correspond to the Retail Funds in which the Plans have in the past invested include the following: the International Equity Fund, U.S. Equity Fund, Strategic Investment Fund, Small-Cap Value Equity Fund, Premier Growth Equity Fund, Value Equity Fund, and Fixed Income Fund.

3. Historically, the investor qualification requirements established by the Institutional Funds precluded the Plans from investing in them. As a result of recent changes to those investor eligibility requirements, however, the Plans may now invest in Class I shares of the Institutional Funds.[18] Certain Plans that previously invested in Retail Funds have chosen to invest in the Institutional Funds that correspond to those Retail Funds, given the lower expense ratios of the

[16] The applicant represents that the Plans were invested in the Retail Funds pursuant to the terms and conditions of Prohibited Transaction Exemption (PTE) 77–3. PTE 77–3 (42 Fed. Reg. 18734, April 8, 1977) is a class exemption that permits, under certain conditions, the acquisition or sale of shares of a registered, open-end investment company by an employee benefit plan covering only employees of such investment company, employees of the investment adviser or principal underwriter for such investment company, or employees of any affiliated person (as defined therein) of such investment adviser or principal underwriter. Thus, the applicant is not requesting exemptive relief with respect to the Plan's past investment in the Retail Funds. The Department expresses no opinion herein as to whether the terms and conditions of PTE 77–3 were satisfied.

[17] According to the applicant, where an Institutional Fund has a corresponding Retail Fund, such Institutional Fund invests in substantially identical underlying securities and substantially the same proportional amounts as its corresponding Retail Fund.

[18] The applicant represents that the changes to the Institutional Funds' investor qualification requirements became effective November 1, 2004. However, the Plans' desired investment changes could not be implemented until certain securities law issues under the 1940 Act were resolved with the no-action relief from the SEC with respect to the in-kind purchases of Institutional Funds shares discussed in Item 5. See GE Institutional Funds (pub. avail. December 21, 2005).

Institutional Funds and the substantial identity in investment objectives and policies between the Retail Funds and the corresponding Institutional Funds. This choice included a decision by the Plans to redeem Class Y Shares of the Retail Funds and to use the proceeds to purchase Class I shares of the corresponding Institutional Funds.

To facilitate investments by the Plans in the Institutional Funds, the Retail Funds and the Institutional Funds determined to permit simultaneous in-kind Redemption and in-kind purchase transactions where possible, and such transactions were effected in March 2006. The applicant represents that this approach benefited the Plans, as well as other shareholders of the Retail Funds and the Institutional Funds, by avoiding the significant brokerage costs that would have been incurred—if portfolio securities of the Retail Funds were sold to realize cash to pay redemption proceeds that were then used to acquire similar portfolio securities in corresponding Institutional Funds. The process of effecting the March 2006 Redemptions began with the commencement of a blackout period applicable to the relevant Plans upon the close of the New York Stock Exchange on March 15, and was completed when the blackout was lifted at 2:30 p.m., Eastern Time, on March 20.

4. With respect to prohibited transaction issues under the Act and the Code, the applicant has requested this exemption to cover the in-kind Redemptions effected in March 2006. Prior to March 2006, the applicant had discussions with the Department, through outside counsel, about obtaining individual retroactive relief for the contemplated Redemptions, modeled on similar prior individual exemptions. The applicant notes that PTE 77–3 provides an exemption for the sale of shares of a mutual fund by an employee benefit plan covering employees of the investment adviser for the mutual fund and its affiliates, subject to certain conditions. However, in several published exemptions, in which the Department has granted individual relief for the in-kind redemption of shares by plans of the investment advisers of mutual funds—*e.g.,* PTE 2003–01 (Northern Trust Company and Affiliates); PTE 2002–20 (Union Bank of California); and PTE 2001–46 (Bank of America Corporation) [19]—the exemption notices describe PTE 77–3 as being available for a redemption of shares for cash, implying that PTE 77–3 would not be available for an in-kind redemption.

The applicant requests retroactive relief for the March 2006 Redemptions and for any other in-kind Redemptions involving the Mutual Funds that are effected prior to the date that an exemption, if granted, is published in the **Federal Register**, as well as prospective relief for any in-kind Redemptions effected on or after that publication date, to be carried out in accordance with the conditions of the exemption.

The applicant is not requesting relief for the in-kind acquisitions of Institutional Funds shares effected in March 2006 (and, it is represented, in the future would be effected) in accordance with PTE 77–3, in reliance on Advisory Opinion 98–06A (July 30, 1998).

5. The applicant represent that, with respect to issues raised under the 1940 Act by the aforementioned transactions, the Retail Funds effected the March 2006 in-kind Redemptions in reliance upon the no-action relief granted by the SEC to Signature Financial Group, Inc. (pub. avail. Dec. 28, 1999) (the Signature Letter).[20] Further, the Institutional Funds obtained no-action relief from the SEC with respect to the in-kind purchases of Institutional Funds shares effected as part of the overall exchange. *See* GE Institutional Funds (pub. avail. December 21, 2005).

According to the applicant, the March 2006 Redemptions were effected pursuant to certain procedures adopted by the Board of Trustees of the Retail Funds, and the in-kind acquisitions were effected pursuant to corresponding procedures adopted by the Board of Trustees of the Institutional Funds. (The same persons serve as members of the Boards of both the Retail Funds and the Institutional Funds.) The securities and cash received by a Plan in an in-kind Redemption from a Retail Fund pursuant to such procedures were used only for the simultaneous purchase of shares of the corresponding Institutional Fund. Any in-kind Redemptions (and simultaneous in-kind acquisitions) occurring in the future would be effected pursuant to the same procedures (the Procedures).

6. Under the Procedures, each in-kind Redemption was effected at the current net asset value per Share of the relevant Retail Fund and was effected simultaneously with the in-kind acquisition of shares of the corresponding Institutional Fund. Pursuant to each in-kind Redemption, subject to the exceptions noted below, a Plan received a pro rata portion of securities of the Retail Fund that was equal in value to the number of Retail Fund Shares redeemed, as determined in a single valuation performed as of 4 p.m. Eastern Time (local time for the closing of the New York Stock Exchange) on the same day, in the same manner as such securities would be valued for purposes of computing the Retail Fund's net asset value per share in accordance with Rule 2a–4 under the 1940 Act and the procedures established by the Board of Trustees of the Retail Funds (using sources independent of GEAM and affiliates of GEAM).[21]

Securities for which quotations are readily available on a national securities exchange are valued at the last quoted sales price, or if there is no reported sale, the security is valued at the last quoted bid price. Certain fixed income securities are valued by a dealer or by a pricing service based upon a computerized matrix system, which considers market transactions and dealer supplied valuations. Valuations for municipal bonds are based on prices obtained from a qualified municipal bond pricing service, which prices are based on the mean of the bid and ask prices of the secondary market. The value of the securities received by the Plan, as determined by the Retail Fund for purposes of an in-kind Redemption, is the same value of such securities that is used in determining the number of Institutional Fund shares purchased by such Plan as a result of the in-kind

[19] The most recent example is PTE 2007–04 (Mellon Financial Corporation).

[20] In the Signature Letter, the Division of Investment Management of the SEC states that it will not recommend enforcement action pursuant to section 17(a) of the 1940 Act for certain in-kind distributions of portfolio securities to an affiliate of a mutual fund. Funds seeking to use this ''safe harbor'' must value the securities to be distributed to an affiliate in an in-kind distribution ''in the same manner as they are valued for purposes of computing the distributing fund's net asset value.''

The Signature Letter does not address the marketability of the securities distributed in kind. The range of securities distributed pursuant to this ''safe harbor'' may therefore be broader than the range of securities covered by SEC Rule 17a–7, 17 CFR 270.17a–7. In granting past exemptive relief with respect to in-kind transactions involving mutual funds, the Department has required that the securities being distributed in-kind fall within Rule 17a–7. One of the requirements of Rule 17a–7 is that the securities are those for which ''market quotations are readily available.'' SEC Rule 17a–7(a). Under this exemption request, exemptive relief also would be limited to in-kind distribution of securities for which market quotations are readily available. In addition, the Signature Letter requires pro rata distributions for any in-kind redemptions.

[21] The applicant further represents that, because each Retail Fund distributed a pro rata portion of every unique lot of every applicable security, the Plans received their proportionate share of each Retail Fund's high tax basis holdings as well as low tax basis holdings of each security distributed in kind. Accordingly, low-basis securities were not disproportionately allocated to the redeeming Plans to any material extent.

purchase that is effected simultaneously as part of the same Redemption/acquisition transaction (and such purchase is effected at the net asset value per share of such Institutional Fund determined as of the same time).

7. Furthermore, under the Procedures, securities received by a Plan pursuant to an in-kind Redemption are limited to securities that are traded on public securities markets or for which quoted bid and asked prices are available from persons independent of GEAM (*i.e.*, Transferable Securities) and do not include the following types of securities or assets: (a) Securities that would have to be registered under the Securities Act of 1933, as amended; (b) securities issued by entities in countries that restrict the holdings of securities by non-nationals, other than through qualified investment vehicles such as the Mutual Funds, or otherwise limit the ability to transfer the security other than through a local securities exchange transaction; and (c) certain portfolio assets (such as forward foreign currency contracts, futures and option contracts, and repurchase agreements) that, although they may be liquid and marketable, involve the assumption of contractual obligations, require special trading facilities, or may only be traded with the counterparty to the transactions in order to effect a change in beneficial ownership. The applicant further represents that no Rule 144A securities were involved in the Redemptions.

In addition, under the Procedures, a Plan receives from the relevant Retail Fund (and deposits to the corresponding Institutional Fund) cash for the portion of the Retail Fund's assets represented by cash equivalents (such as certificates of deposit, commercial paper, and repurchase agreements). A Plan receives from the relevant Retail Fund (and deposits to the corresponding Institutional Fund) cash for other securities and assets that are not readily distributable (including securities and assets of the types described in (a), (b) and (c) of the preceding paragraph, receivables, and prepaid expenses) net of a pro rata portion of all liabilities (including accounts payable), and for those portfolio securities not amounting to round lots (e.g., 100 shares) (or would not amount to round lots if included in the in-kind Redemption and purchase) or fractional shares and accruals on these securities.

The applicant represents that the March Redemptions also satisfied the remaining conditions set forth in Section I not addressed above. Thus, for example, neither GEAM nor a GEAM Affiliate, received any fees (including any fees pursuant to Rule 12b–1 under the 1940 Act) in connection with any in-kind Redemption.

8. Further, the applicant retained U.S. Trust Company, N.A. (U.S. Trust), a national bank, to act as the Independent Fiduciary on behalf of the Plans with regard to the March 2006 Redemptions. It is represented that U.S. Trust is independent of, and unrelated to, GEAM and GEAM Affiliates and is qualified to perform the functions of the Independent Fiduciary. U.S. Trust has acknowledged that it is a fiduciary to the Plans, as defined in section 3(21) of the Act, and has represented that it understands and accepts the duties, responsibilities, and liabilities in acting as a fiduciary under the Act for the Plan, pursuant to the terms of an engagement letter, dated December 20, 2005, by and between GEAM and U.S. Trust.

As a condition of the proposed exemption, prior to any in-kind Redemption with respect to a Plan, GEAM and the Plan must provide the Independent Fiduciary with (or cause the Independent Fiduciary to be provided with) information necessary for the Independent Fiduciary to determine the fairness of the proposed in-kind Redemption. Before authorizing any in-kind Redemption, the Independent Fiduciary must determine, based on the information provided, that the terms of the in-kind Redemption are fair to the participants of the Plan and are comparable to, and no less favorable than, terms obtainable at arm's length between unaffiliated parties, and that the in-kind Redemption is in the best interests of the Plan and its participants and beneficiaries. If the Independent Fiduciary makes that determination, the Independent Fiduciary provides written authorization for such in-kind Redemption to GEAM. However, that authorization is terminable at any time prior to the date of the in-kind Redemption, without penalty to the Plan.

U.S. Trust also conducted a post-transaction review, summarized in a letter dated September 5, 2006, within 180 days of the date of the March 2006 Redemptions. The post-transaction review confirmed that the transfer was carried out in accordance with the required criteria and procedures, by testing a sampling of certain material aspects of the redemption transactions.[22] U.S. Trust states,

In the Pre-Trade analysis performed by GEAM, the costs to redeem in cash and repurchase all of the securities from the Funds to the corresponding GE Institutional Funds were estimated to be $435,612.34 combined for commissions, spread, taxes and fees. By completing the redemption and reinvestment in kind rather than in cash these costs were avoided. The Plans were immediately reinvested after the in kind redemption; therefore, potential opportunity costs associated with reinvestment risk were eliminated. If the Plans had received cash instead of their pro rata portion of the assets in each of the Funds, they would have been forced to incur their pro rata portion of the sell side transactions costs, and they would have had to incur all of the buy side transactions costs when they reinvested the proceeds. Furthermore, there may have been a time lag from the date of the redemption request to the time the Plans had fully redeployed the proceeds. This time lag would have imposed an opportunity cost by not being invested in securities that would have had the potential to match the Plans [sic] stated objectives.

With respect to any future Redemptions, as a condition of the proposed exemption, the Independent Fiduciary will also perform such a post-transaction review within 180 days of the date of the Redemption.

9. In summary, the applicant represents that the Redemptions have satisfied, and will satisfy, the statutory criteria for an exemption under section 408(a) of the Act for the following reasons:

(A) The Plan pays no sales commissions, redemption fees, or other similar fees in connection with the Redemption (other than customary transfer charges paid to parties other than GEAM and GEAM Affiliates);

(B) The assets transferred to the Plan pursuant to the Redemption consist entirely of cash and Transferable Securities;

(C) With certain exceptions described below, the Plan receives in any Redemption its pro rata portion of the securities that, when added to the cash received, is equal in value to the number of Shares redeemed, as determined in a single valuation performed in the same manner and as of 4 p.m. (local time for the New York Stock Exchange) on the same day, in accordance with Rule 2a–4 under the 1940 Act, and the then-existing procedures established by the Board of Trustees of the Mutual Fund (using sources independent of GEAM and GEAM Affiliates). Notwithstanding the foregoing, Transferable Securities that are odd lot securities, fractional shares, and accruals on such securities may be distributed in cash;

(D) Neither GEAM, nor any GEAM Affiliate, receives any direct or indirect

[22] Condition (J) in Section I refers to testing ''a sampling'' of material aspects of the Redemptions by the Independent Fiduciary. The applicant represents, however, that U.S. Trust received and reviewed all of the data in connection with the Redemptions, thus reviewing 100% of the security transactions, not merely a sampling.

compensation, or any fees, including any fees payable pursuant to Rule 12b–1 under the 1940 Act, in connection with any Redemption of the Shares;

(E) Prior to a Redemption, GEAM provides in writing to an Independent Fiduciary a full and detailed written disclosure of information regarding the Redemption;

(F) Prior to a Redemption, the Independent Fiduciary provides written authorization for such Redemption to GEAM, such authorization being terminable at any time prior to the date of Redemption without penalty to the Plan;

(G) Before authorizing a Redemption, based on the disclosures provided by GEAM to the Independent Fiduciary, the Independent Fiduciary determines that the terms of the Redemption are fair to the Plan, and comparable to, and no less favorable than, terms obtainable at arm's length between unaffiliated parties, and that the Redemption is in the best interests of the Plan and its participants and beneficiaries;

(H) Not later than thirty (30) business days after the completion of a Redemption, the Mutual Fund will provide to the Independent Fiduciary a written confirmation regarding such Redemption containing:

(i) The total number of Shares of the Mutual Fund and the percentage held by the Plan immediately before the Redemption (and the related per Share net asset value and the total dollar value of the Shares held);

(ii) The identity (and related aggregate dollar value) of each security provided to the Plan pursuant to the Redemption, including each security valued in accordance with Rule 2a–4 under the 1940 Act and the then-existing procedures established by the Board of Trustees of the Mutual Fund (using sources independent of GEAM and GEAM Affiliates);

(iii) The current market price of each security received by the Plan pursuant to the Redemption; and

(iv) The identity of each pricing service or market-maker consulted in determining the value of such securities;

(I) The value of the securities received by the Plan for each redeemed Share, when added to the cash received, equals the net asset value of such Share at the time of the transaction, and such value equals the value that would have been received by any other investor for shares of the same class of the Mutual Fund at that time;

(J) Subsequent to a Redemption, within 180 days of the date of such Redemption, the Independent Fiduciary performs a post-transaction review that will include, among other things, testing a sampling of material aspects of the Redemption deemed in its judgment to be representative, including pricing;

(K) Each of the Plan's dealings with the Mutual Funds, the investment advisers to the Mutual Funds, the principal underwriter for the Mutual Funds, or any affiliated person thereof, are on a basis no less favorable to the Plan than dealings between the Mutual Funds and other shareholders holding shares of the same class as the Shares.

Notice To Interested Persons: Notice of the proposed exemption will be given to the relevant named fiduciary of each Plan and to the Independent Fiduciary representing the Plans by first class mail within 30 days from the date of publication of the proposed exemption in the **Federal Register**. Comments and requests for a hearing from all interested persons are due within 60 days from such date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Karin Weng of the Department, telephone (202) 693–8557. (This is not a toll-free number.)

Middleburg Trust Company (Middleburg) Located in Richmond, VA

[Application No. D–11405]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990).[23]

If the exemption is granted, the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the past sale, on March 28, 2006, by the William T. Smith IRA (the IRA) of certain bonds (the Bonds) to Middleburg, a disqualified person with respect to the IRA.

This proposed exemption is conditioned upon adherence to the material facts and representations described herein and upon satisfaction of the following conditions:

(a) The sale was a one-time transaction for cash;

(b) The sale price for the Bonds was based on the Bonds' face value;

(c) The Bonds' face value was in excess of bids for the Bonds solicited from independent brokers and in excess of the price for the Bonds quoted by an independent valuation service for the date of the sale;

(d) Neither the IRA nor Mr. William T. Smith, the owner of the IRA, paid any fees, commissions, or other costs or expenses associated with the sale;

(e) The IRA received its portion of income and all interest accrued on the Bonds through the date of the sale;

(f) The terms and conditions of the sale were at least as favorable to the IRA as those obtainable in an arm's length transaction with an unrelated party; and

(g) Within 30 days of the publication of the grant notice in the **Federal Register**, Middleburg will pay the IRA $196.53 to make up for the loss sustained by the IRA as a result of the sale.

Effective Date: If granted, the proposed exemption will be effective as of March 28, 2006.

Summary of Facts and Representations

1. The plan to which the proposed exemption applies is an individual retirement account described under section 408(a) of the Code. The IRA is a ''traditional IRA'' in that the custodian, rather than the IRA account holder, makes the investment decisions for such plan. Mr. William T. Smith is the IRA account holder. As of February 28, 2006, the IRA had total assets having a fair market value of $578,193.89.

Middleburg,[24] an independent trust company, headquartered in Richmond, Virginia, formerly acted as the custodian and trustee of the IRA and had discretion over the IRA's assets. At no time did Mr. Smith ever serve as an officer, director, or employee of Middleburg or its affiliates or have any other relationship with these entities.

2. On June 28, 2005, Middleburg purchased 200 Federal Home Loan Bank (FHLB) bonds having a combined face value of $200,000.00.[25] Each Bond in the entire issue had a Committee on Uniform Securities Identification Procedures Number of 3133XB2C8. Middleburg paid a total purchase price of $201,600 for the Bonds. The seller of the Bonds was First Tryon Securities of Charlotte, North Carolina, an unrelated party. Each Bond was issued in denominations of $1,000. The Bonds carry interest at 5% and have a maturity date of March 28, 2008. The Bonds were

[23] Pursuant to 29 CFR 2510.3–2(d), the IRA is not within the jurisdiction of Title I of the Employee Retirement Income Security Act of 1974 (the Act). However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Code.

[24] Prior to its name change, which took effect on January 1, 2006, Middleburg was known as ''Tredegar Trust Company.''

[25] FHLB bonds are issued in denominations of $1,000 each, usually with minimum purchase amounts of 5 bonds ($5,000 face). Some FHLB bonds are issued for the institutional market, requiring a 100 bonds minimum ($100,000 face). The bonds normally pay a stated fixed coupon (interest) and will pay face value at maturity or at an optional call date.

divided among nine accounts (i.e., trust accounts and two IRAs, including the subject IRA) that needed fixed income exposure. Middleburg was the trustee for all nine accounts. Middleburg placed $25,200.00 of the Bond issue (or 25 Bonds) in the IRA. Thus, the Bonds represented approximately 4.3% of the IRA's assets. Middleburg allocated the Bonds among the remaining accounts based on a pro rata share of their fair market value, in conjunction with the need in the account portfolios for fixed income exposure.

3. In February 2006, Mr. Smith decided to move his IRA to another custodian. As a result, he requested that Middleburg liquidate all of his IRA holdings in order to transfer cash to the new custodian. While attempting to liquidate the Bonds held by the IRA, Middleburg discovered that the issue would trade only in $100,000.00 blocks. Middleburg represents that the salesman neglected to mention this limitation when the Bonds were first purchased. As a result, this limitation made the Bonds held in the IRA illiquid.

4. In order to satisfy Mr. Smith's request, Middleburg decided that it needed to make a market for the Bonds held in the IRA. To ensure that the transaction would occur on terms that were at least as favorable as an arm's length sale to a third party, Middleburg represents that it solicited bids as if it had $100,000.00 worth of the Bonds to sell. The bids from various independent dealers ranged from $99.50 to $99.80 per $100.00 of Bond value, or $99,500 to $99,800, respectively. In addition, Middleburg advertised the Bonds all day on March 28, 2006.

5. Middleburg decided that it would buy the Bonds held by the IRA at their full face value of $100 per $100 of Bond value, which exceeded the fair market value at the time. In this regard, the Bond's fair market value, as quoted by Bloomberg Fair Value Service on March 28, 2006, the trade date, was $99.87 per $100 of Bond value or $24,968 for the Bonds. Thus, Middleburg paid the IRA $25,000.00, plus accrued interest of $3.47, or a total purchase price of $25,003.47 for the Bonds. Middleburg did not charge the IRA any fees or commissions in connection with the transaction. Because the IRA sustained a loss as a result of the sale, Middleburg will pay the IRA $196.53 within 30 days of the publication of the grant notice in the **Federal Register**.

6. In summary, Middleburg represents that the subject transaction satisfied or will satisfy the statutory criteria for an exemption under section 4975(c)(2) of the Code for the following reasons: (a) The sale was a one-time transaction for cash; (b) the sale price for the Bonds was based on the Bonds' face value; (c) the Bonds' face value was in excess of bids for the Bonds solicited from independent brokers and in excess of the price for the Bonds quoted by an independent valuation service for the date of the sale; (d) the IRA paid no fees, commissions, or other costs or expenses associated with the sale; (e) the IRA received its portion of income and all interest accrued on the Bonds through the date of the sale; (f) the terms and conditions of the sale were at least as favorable to the IRA as those obtainable in an arm's length transaction with an unrelated party; and (g) within 30 days of the publication of the grant notice in the **Federal Register**, Middleburg will pay the IRA $196.53 to make up for the loss sustained by the IRA as a result of the sale.

Notice to Interested Persons

Because Mr. Smith is the only participant in the IRA, it has been determined that there is no need to distribute the notice of proposed exemption to interested persons. Therefore, comments and requests for a hearing must be received by the Department within 30 days of the date of publication of the proposed exemption in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Blessed Chuksorji of the Department, telephone number (202) 693–8567. (This is not a toll-free number.)

Citigroup, Inc. (Citigroup) Located in New York, NY

[Application No. D–11417]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act (or ERISA) and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990.)

Section I: Covered Transactions

If the proposed exemption is granted, the restrictions of sections 406(a)(1)(D) and 406(b) of ERISA and the sanctions resulting from the application of section 4975 of the Code, including the loss of exemption of an IRA pursuant to section 408(e)(2)(A) of the Code, by reason of section 4975(c)(1)(D), (E) and (F) of the Code, shall not apply to the receipt of services at reduced or no cost by an individual for whose benefit an IRA or, if self-employed, a Keogh Plan, is established or maintained, or by members of his or her family, from Citigroup pursuant to an arrangement in which the account value of, or the fees incurred for services provided to, the IRA or Keogh Plan is taken into account for purposes of determining eligibility to receive such services, provided that each condition of Section II of this exemption is satisfied.

Section II: Conditions

(a) The IRA or Keogh Plan whose account value, or whose fees paid, are taken into account for purposes of determining eligibility to receive services under the arrangement must be established and maintained for the exclusive benefit of the participant covered under the IRA or Keogh Plan, his or her spouse or their beneficiaries.

(b) The services offered under the arrangement must be of a type that a qualified affiliate could offer consistent with all applicable federal and state banking laws and all applicable federal and state laws regulating broker-dealers.

(c) The services offered under the arrangement must be provided by a qualified affiliate in the ordinary course of its business as a bank or a broker-dealer to customers who qualify for reduced or no cost services, but do not maintain IRAs or Keogh Plans with a qualified affiliate.

(d) For the purpose of determining eligibility to receive services, the arrangement satisfies:

(i) Eligibility requirements based on the account value of the IRA or Keogh Plan are as favorable as any such requirement based on the value of any other type of account which the qualified affiliate includes to determine eligibility; and/or

(ii) Eligibility requirements based on the amount of fees incurred by the IRA or Keogh Plan, are as favorable as any requirements based on the amount of fees incurred by any other type of account which the qualified affiliate includes to determine eligibility.

(e) The combined total of all fees for the provision of services to the IRA or Keogh Plan is not in excess of reasonable compensation within the meaning of section 408(b)(2) of ERISA and section 4975(d)(2) of the Code.

(f) The investment performance of the investments made by the IRAs and/or Keogh Plans is no less favorable than the investment performance of identical investments that could have been made at the same time by a customer of Citigroup who is not eligible for (or who does not receive) reduced or no cost services.

(g) The services offered under the arrangement to the IRA or Keogh Plan customer must be the same as are offered to non-IRA or non-Keogh Plan customers of qualified affiliates with

account values of the same amount or the same amount of fees generated.

Section III: Definitions

The following definitions apply to this exemption:

(a) The term ''bank'' means a bank described in section 408(n) of the Code.

(b) The term ''broker-dealer'' means a broker-dealer registered under the Securities Exchange Act of 1934, as amended.

(c) The term ''IRA'' means an individual retirement account described in Code section 408(a), an individual retirement annuity described in Code section 408(b) or a Coverdell education savings account described in section 530 of the Code. For purposes of this exemption, the term IRA shall not include an IRA which is an employee benefit plan covered by Title I of ERISA, except for a Simplified Employee Pension (SEP) described in section 408(k) of the Code or a Simple Retirement Account described in section 408(p) of the Code which provides participants with the unrestricted authority to transfer their balances to IRAs or Simple Retirement Accounts sponsored by different financial institutions.

(d) The term ''Keogh Plan'' means a pension, profit-sharing, or stock bonus plan qualified under Code section 401(a) and exempt from taxation under Code section 501(a) under which some or all of the participants are employees described in section 401(c) of the Code. For purposes of this exemption, the term Keogh Plan shall not include a Keogh Plan which is an employee benefit plan covered by Title I of ERISA.

(e) The term ''account value'' means investments in cash or securities held in the account for which market quotations are readily available. For purposes of this exemption, the term cash shall include savings accounts that are insured by a federal deposit insurance agency and constitute deposits as that term is defined in 29 CFR 2550.408b–4(c)(3). The term account value shall not include investments that are offered by Citigroup (or a qualified affiliate) exclusively to IRAs and Keogh Plans.

(f) The term ''qualified affiliate'' means any person directly or indirectly controlling, controlled by, or under common control with Citigroup Inc. that is a bank or broker-dealer.

(g) The term ''members of his or her family'' refers to beneficiaries of the individual for whose benefit the IRA or Keogh Plan is established or maintained, who would be members of the family as that term is defined in Code section 4975(e)(6), or a brother, a sister, or a spouse of a brother or sister.

(h) The term ''service'' includes incidental products of a de minimis value which are directly related to the provision of services covered by the exemption.

(i) The term ''fees'' means commissions and other fees received by a broker-dealer from the IRA or Keogh Plan for the provision of services, including, but not limited to, brokerage commissions, investments management fees, investments advisory fees, custodial fees and administrative fees.

(j) The term ''Citigroup'' means Citigroup Inc. and any person directly or indirectly controlling, controlled by, or under common control with Citigroup Inc.

(k) The term ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

Effective Date: If granted, this proposed exemption will be effective as of March 1, 2007.

Summary of Facts and Representations

1. Citigroup, Inc. is a holding company whose businesses provide a broad range of financial services to consumer and corporate customers around the world. As of September 30, 2006, Citigroup and its subsidiaries had total consolidated assets of approximately $1.75 trillion. Citigroup's consumer and corporate banking business is a global franchise encompassing, among other things, branch and electronic banking, consumer lending services, investment services, and credit and debit card services. Citigroup also provides securities trading, research and brokerage services to consumer and corporate customers, primarily through its Smith Barney business. Smith Barney, a division of a subsidiary of Citigroup Inc., is a retail brokerage firm with more than 12,500 financial advisors who serve approximately 7.1 million client accounts, representing approximately $1.3 trillion in assets, and are located in approximately 600 offices across the United States. In the ordinary course of its business, Citigroup provides a range of financial services to IRAs and pension, profit sharing and stock bonus plans qualified under section 401(a) of the Code under which some or all of the participants are employees described in section 401(c) of the Code.

2. PTE 93–33 as amended (64 FR 11044, March 8, 1999), provides relief from the restrictions of sections 406(a)(1)(D) and 406(b) of ERISA and the sanctions resulting from the application of sections 4975(a) and (b), 4975(c)(3) and 408(e)(2) of the Code by reason of section 4975(c)(1)(D), (E) and (F) of the Code, and permits the receipt of services at reduced or no cost by an individual for whose benefit an IRA or Keogh Plan is established or maintained or by members of his or her family, from a bank pursuant to an arrangement in which the account balance of the IRA or Keogh Plan is taken into account for purposes of determining eligibility to receive such services, provided the conditions of the exemption are met. PTE 93–33 permitted banks to offer its customers only those services that may be offered by banks under applicable federal and state banking laws.[26] In the case where the service is offered by an affiliate of the bank, the service must be of the type that the bank itself could offer customers.

PTE 97–11 as amended, (67 FR 76425, December 12, 2002) permits the receipt of services at reduced or no cost by an individual for whose benefit an IRA or Keogh Plan is established or maintained or by members of his or her family, from a broker-dealer registered under the Securities Exchange Act of 1934 pursuant to an arrangement in which the account value of, or the fees incurred for services provided to, the IRA or Keogh Plan is/are taken into account for purposes of determining eligibility to receive such services, provided that certain conditions are met. Under PTE 97–11 relief is provided from the restrictions of sections 406(a)(1)(D) and 406(b) of ERISA and the sanctions resulting from the application of sections 4975(a) and (b), 4975(c)(3) and 408(e)(2) of the Code by reason of section 4975(c)(1)(D), (E) and (F) of the Code. PTE 97–11 limits the services that may be offered by broker-dealers under a relationship brokerage program to those services that the broker-dealer itself may offer consistent with federal and state laws regulating broker-dealers.[27] Furthermore, in those

[26] In the notice of proposed exemption for PTE 93–2 (PTE 93–33 subsequently amended PTE 93–2) the following examples of relationship banking services were listed: free checking services, discounted safe deposit box rents, or free loan closing costs. (52 FR 8365 (February 28, 1992)). In addition, the Department notes that a bank may offer other services or benefits to customers as part of its relationship banking program. For example, under PTE 93–33 a bank may offer its relationship banking customers a higher interest rate on their investments, provided the conditions of the exemption are met.

[27] In the notice of proposed exemption for PTE 97–11 (61 FR 39996 (July 31, 1996), the following examples of relationship brokerage services were listed: financial planning services, direct deposit/debit and automatic fund transfer privileges, enhanced account statements, toll-free access to client service center, check writing privileges, debit/credit cards, special newsletter and reduced brokerage and asset management fees. In addition,

cases where the services are provided by an affiliate of the broker-dealer, the service must be the type that the broker-dealer itself could offer customers.

The applicant requests an exemption to permit both account balances of an IRA or Keogh Plan or fees incurred by the IRA or Keogh Plan with respect to a qualified affiliate that serves as trustee or custodian, to be taken into account by Citigroup in determining eligibility to receive reduced or no cost services that are provided by its qualified affiliates.

3. The applicant represents that the proposed exemption is necessary and appropriate because federal and state banking and securities laws have undergone changes since PTEs 93–33 and 97–11 were granted. In general, banks and broker-dealers are now permitted to offer services to its customers that integrate banking and broker-dealer type services. These services were traditionally provided either by a bank to its customers or by a broker-dealer to its customers. Specifically, PTEs 93–33 and PTE 97–11 were granted by the Department prior to the enactment of the Gramm-Leach-Bliley Act of 1999 (the ''GLBA''). According to the applicant, the GLBA altered the U.S. legal and regulatory framework governing the operations of U.S. bank holding companies such as Citigroup, the corporate parent of Citibank, N.A. (''Citibank'') and Citigroup Global Capital Markets Inc. (''CGMI''), the broker-dealer within which Smith Barney operates as a business division. The applicant represents that the GLBA permits bank holding companies that qualify as ''financial holding companies'' (''FHCs'')—including Citigroup—to affiliate broadly with various types of financial services firms, including full-service U.S. broker-dealers. Further, the enactment of the GLBA has greatly facilitated both financial services integration in the United States and the growth of bank-affiliated securities operations.

According to the applicant, a second significant U.S. regulatory development occurred in 1995 when the U.S. Federal Reserve Board (the FRB) adopted a rule regarding inter-affiliate combined balance discount service programs offered to individual customers of banks and bank affiliates.[28] In particular, the rule establishes a safe harbor (the ''Safe Harbor'') from the statutory restrictions on bank tying arrangements to allow banks greater flexibility to package products with their affiliates. The applicant states that the rule provided important validation of the ability of banks and their broker-dealer affiliates to offer to their customers' combined-balance discount programs meeting the requirements of the Safe Harbor. Furthermore, the applicant represents that in 1997, the FRB reaffirmed the Safe Harbor when it re-wrote its Regulation Y, which includes a section dealing with anti-tying restrictions. In this regard, the applicant represents that the reduced or no cost service program described in its exemption application meets the Safe Harbor.

In the context of the regulatory developments described above, the applicant states that Citigroup's decision to offer discount services as described in its application reflects the important changes in Citigroup's business model that have occurred since PTEs 93–33 and 97–11 were granted by the Department. The applicant states that in 1998, Citigroup was created through the acquisition of Citicorp, Citibank's corporate parent, by Travelers Group, to form Citigroup. As part of this transaction, Citibank became affiliated with Smith Barney (formerly, Salomon Smith Barney), which operates a significant retail securities brokerage business.[29] As a result, Citigroup developed programs that link retail banking activities with retail brokerage activities. Under these arrangements, qualified affiliates are able to take into account a customer's combined balance maintained with any of its affiliates in determining the customer's eligibility to receive reduced or no cost services that include bank and broker-dealer products and services.

4. The transactions covered by the proposed exemption are the receipt of services at reduced or no cost by an individual for whose benefit an IRA or, if self-employed, a Keogh Plan account, is established or maintained, or by members of his or her family, from Citigroup, pursuant to an arrangement in which the account balance of, or fees paid by, the IRA or Keogh Plan account is taken into account for purposes of determining eligibility to receive the reduced or no cost services. The proposed exemption does not apply to IRAs or Keogh Plans that are covered by Title I of ERISA except for a Simplified Employee Pension (SEP) described in section 408(k) of the Code or a Simple Retirement Account described in section 408(p) of the Code which provides participants with the unrestricted authority to transfer their balances to IRAs or Simple Retirement Accounts sponsored by different financial institutions. The IRA or Keogh Plan account must be established or maintained for the exclusive benefit of the participant covered by the IRA or Keogh Plan, or his family members. The services must be of a type that either a bank or broker-Dealer could offer consistent with all federal and state laws applicable to their businesses. Citigroup provides such services to its customers, including customers who do not maintain IRAs or Keogh Plans with Citigroup, in the regular course of Citigroup's business. The account balance or fee level required for the receipt of reduced or no cost services is equal to the lowest level required for any other type of account which is used to determine eligibility to receive reduced or no cost services. The investment performance of the IRA or Keogh Plan account's investments is no less favorable than the investment performance of identical investments that could have been made at the same time by a customer who is not eligible for (or who does not receive) reduced or no cost services.

5. As part of its reduced or no cost service program, the applicant contemplates providing such services as: Reductions or waivers of fees for services such as checking, ATM, investment advisory and account opening or maintenance fees, preferred lending rates, premium interest crediting rates, credit or debit cards providing services such as enhanced mileage accumulation and reward points features and the provision of investment information and seminars that are available on an invitation-only basis. In this regard, the applicant offers the following example of a reduced or no cost service program:

An individual client of Citigroup is a beneficial owner of an IRA with assets of $250,000 and with respect to which Smith Barney is custodian. Un-invested cash in the IRA is swept into a bank deposit program (''BDP'') on a daily basis, pursuant to the client's instruction. Assume that the client also maintains a Smith Barney Financial Management Account (''FMA Account''), a securities brokerage account, with an asset balance of $200,000, as well as personal savings and checking accounts, with an aggregate asset balance of $100,000, at Citibank. Without the proposed exemption, the client is not eligible for ''Reserved'' status in regard to the relationship with his Smith Barney custodied accounts (FMA Account

the Department notes that a broker-dealer may offer its customers additional services and benefits as part of its relationship brokerage program. For example, under PTE 97–11, a broker-dealer may offer its relationship brokerage customers a higher interest rate on their investments, provided the conditions of the exemption are met.

[28] See 12 CFR 225.7(b)(2).

[29] The applicant states that Citibank's pre-GLBA-era securities businesses were principally institutional in nature (e.g., underwriting and dealing in certain securities subject to pre-GLBA restrictions and other wholesale capital markets activities).

and IRA), which status requires asset balances of at least $500,000. As a result, the client would be charged a $100 annual fee in respect of the FMA Account and a $40 annual fee in respect of the IRA. The IRA's BDP investments would receive interest at a rate applicable to accounts having asset balances between $250,000 and $500,000, which rate was 3.35% Annual Percentage Yield as of June 13, 2007.

If the proposed exemption is granted, Citigroup would be permitted to aggregate the client's accounts (in accordance with the conditions of the exemption), and the combined asset balance in excess of $500,000 would result in an elimination of the $100 and $40 annual fees. In addition, the BDP investments would be eligible for a higher interest rate, equal to 3.51% Annual Percentage Yield as of June 13, 2007. Further, as part of a Reserved relationship, Smith Barney would waive the following fees (among others) in the client's FMA Account: ATM fees, shipping costs for lost or stolen cards, fees for transferring securities, safekeeping fees for physically holding securities, Fed wire fees, fees charged for bounced checks, fees charged to stop payment on a check, and check reorder fees.

6. In summary, the Applicant represents that the transactions will satisfy the statutory criteria for an exemption under section 408(a) of the Act and section 4975(c)(2) since, among other things:

(a) The IRA or Keogh Plan whose account value, or whose fees paid, are taken into account for purposes of determining eligibility to receive services under the arrangement will be established and maintained for the exclusive benefit of the participant covered under the IRA or Keogh Plan, his or her spouse or their beneficiaries.

(b) The services offered under the arrangement will be of a type that a qualified affiliate could offer consistent with all applicable federal and state banking laws and all applicable federal and state laws regulating broker-dealers.

(c) The services offered under the arrangement will be provided by a qualified affiliate in the ordinary course of its business as a bank or a broker-dealer to customers who qualify for reduced or no cost services, but do not maintain IRAs or Keogh Plans with a qualified affiliate.

(d) For the purpose of determining eligibility to receive services, the arrangement will satisfy:

(i) Eligibility requirements based on the account value of the IRA or Keogh Plan are as favorable as such requirements based on the value of any other type of account which the qualified affiliate includes to determine eligibility; and/or

(ii) Eligibility requirements based on the amount of fees incurred by the IRA or Keogh Plan, are as favorable as any requirements based on the amount of fees incurred by any other type of account which the qualified affiliate includes to determine eligibility.

(e) The combined total of all fees for the provision of services to the IRA or Keogh Plan will not be in excess of reasonable compensation within the meaning of section 408(b)(2) of ERISA and section 4975(d)(2) of the Code.

(f) The investment performance of the investments made by the IRAs and/or Keogh Plans will be no less favorable than the investment performance of identical investments that could have been made at the same time by a customer of Citigroup who is not eligible for (or who does not receive) reduced or no cost services.

(g) The services offered under the arrangement to the IRA or Keogh Plan customer will be the same as are offered to non-IRA or non-Keogh Plan customers of qualified affiliates with account values of the same amount or the same amount of fees generated.

Notice to Interested Persons

The Applicant represents that because those potentially interested persons cannot all be identified at the time this proposed exemption is published in the **Federal Register**, the only practical means of notifying the public is by publication of the notice of pendency in the **Federal Register**. Therefore, written comments and/or requests for a public hearing must be received by the Department not later than 45 days from the date of publication of this notice of proposed exemption in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Allison Padams-Lavigne, U.S. Department of Labor, telephone (202) 693–8564. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which, among other things, require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries, and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Ivan Strasfeld,

Director of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. E7–20921 Filed 10–25–07; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,023]

Benchmark Electronics, Inc.

Loveland Division, Including On-Site Leased Workers of Volt Services Group Who Were Retained by Verigy US Development, Loveland, Colorado; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and section 246 of the Trade Act of 1074 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on October 27, 2006,

applicable to workers of Benchmark Electronics, Inc., Loveland Division, including on-site leased workers from Volt Services Group, Loveland, Colorado. The notice was published in the **Federal Register** on November 16, 2006 (71 FR 66799).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production (assemble, test, etc.) of flash memory test systems.

New information shows that when Benchmark Electronics, Inc., Loveland Division, closed in November 2006, a customer, Verigy US Development, retained the on-site leased workers from Volt Services Group to complete their outstanding orders of flash memory test systems.

Accordingly, the Department is amending the certification to include on-site leased workers who were retained by Verigy US Development.

The intent of the Department's certification is to include all workers of Benchmark Electronics, Inc., Loveland Division who were adversely affected by increased customer imports.

The amended notice applicable to TA–W–60,023 is hereby issued as follows:

''All workers of Benchmark Electronics, Inc., Loveland Division, including on-site leased workers from Volt Services Group who were retained by Verigy US Development, Loveland, Colorado, who became totally or partially separated from employment on or after September 6, 2005, through October 27, 2008, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.''

Signed at Washington, DC this 17th day of October 2007.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–21185 Filed 10–25–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–62,073]

Fujitsu Ten Corporation of America, Rushville Indiana Operations Including On-Site Leased Workers of Personnel Management, Inc. and Penmack Rushville, Indiana; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on October 11, 2007, applicable to workers of Fujitsu Ten Corporation of America, Rushville Indiana Operations, including on-site leased workers of Personnel Management, Inc., Rushville, Indiana. The notice will be published soon in the **Federal Register**.

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of automotive electronic controls.

The review of the investigation record shows that the Department inadvertently excluded from the certification on-site leased workers from Penmack.

Accordingly, the Department is amending this certification to include on-site leased workers from Penmack. The workers of Penmack at the Rushville site are sufficiently under the control of Fujitsu Corporation of America to be considered leased workers.

The amended notice applicable to TA–W–62,073 is hereby issued as follows:

''All workers of Fujitsu Ten Corporation of America, Rushville Indiana Operations, including on-site leased workers of Personnel Management, Inc. and Penmack, Rushville, Indiana, who became totally or partially separated from employment on or after August 28, 2006, through October 11, 2009, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.''

Signed at Washington, DC this 23rd day of October 2007.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–21188 Filed 10–25–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of *October 9 through October 12, 2007.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. the sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. there has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. the country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. there has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) a loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

Affirmative Determinations For Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) of the Trade Act have been met.

Ta–W–62,205; Gemtron Corporation, Holland, MI: November 11, 2007.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) of the Trade Act have been met.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–61,978; PCS Company, Pins Department, Federal Signal Corp, Fraser, MI: July 30, 2006.

TA–W–62,053; Sunrise Medical Incorporation, Devilbiss Healthcare, Kelly Services, Somerset, PA: August 27, 2006.

TA–W–62,116; U.S. Textile Corporation, Newland, NC: September 8, 2007.

TA–W–62,157; Johnston Textiles, Inc., Micolas Division, Opp, AL: September 17, 2006.

TA–W–62,219; Creative Interiors, aka TFI Carysbrook Plant, Fork Union, VA: September 27, 2006.

TA–W–62,250; Vaughan Furniture Company, Inc., Galax, VA: October 3, 2006.

TA–W–61,871; Dirigo Paper Company, Prometheus Power Co, Gilman, VT: July 23, 2006.

TA–W–62,016; Mohawk Industries, Inc., Karastan Division, On-Site Leased Workers From Ameristaff, Eden, NC: August 20, 2006.

TA–W–62,138; Maine Fence Company, World Wide Personnel/ASMARA Human Resources, Pittsfield, ME: September 11, 2006.

TA–W–62,176; First American Title Insurance Co, Eagle Production Center, Flint, MI.

TA–W–62,262; Summit Switching, Working On-Site At Ford Motor Company, Chesapeake, VA: October 4, 2006.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–62,073; Fujitsu Ten Corporation of America, Rushville Indiana Operations, On-Site Leased Workers of Personnel Management, Rushville, IN: August 28, 2006.

TA–W–62,074; Playtex Puerto Rico/Sara Lee Branded Apparel, Vega Baja, PR: August 29, 2006.

TA–W–62,078; Colgate Palmolive, Inc., Guayama, PR: August 29, 2006.

TA–W–62,201; Head Lites Corp, Woodbury, MN: September 25, 2006.

TA–W–62,248; ArvinMeritor, Gabriel Ride Control Division, Chickasha, OK: October 3, 2006.

TA–W–62,261; American Uniform Company, Headquarters/Cleveland Div., Cleveland, TN: December 4, 2006.

TA–W–62,059; M/A-Com, Inc., A Division of Tyco Electronics, IC Department & Component Group Department, Lowell, MA: August 24, 2006.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–62,032; DGS Stampings, Inc., Cleveland, OH: August 15, 2006.

TA–W–62,140; R.E. Phelon Company, Inc., On-Site Leased Workers From Aiken Staffing and Manpower, Aiken, SC: September 11, 2006.

TA–W–62,140A; Manufacturing Performance Services, LLC, Aiken, SC: September 11, 2006.

The following certifications have been issued. The requirements of Section

222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

None.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of Section 246 has not been met. The firm does not have a significant number of workers 50 years of age or older.

TA–W–62,205; Gemtron Corporation, Holland, MI.

The Department has determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable.

None.

The Department has determined that criterion (3) of Section 246 has not been met. Competition conditions within the workers' industry are not adverse.

None.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

None.

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

None.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–62,033; Textile Arts and Film, Inc., Chester, SC.

TA–W–62,102; Network Appliance, Inc., Sunnyvale, CA.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–62,176; First American Title Insurance Co, Eagle Production Center, Flint, MI.

The investigation revealed that criteria of Section 222(b)(2) has not been met. The workers' firm (or subdivision) is not a supplier to or a downstream producer for a firm whose workers were certified eligible to apply for TAA.

None.

I hereby certify that the aforementioned determinations were issued during the period of *October 9 through October 12, 2007.* Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: October 19, 2007.

Ralph DiBattista,

Director, Division of Trade Adjustment Assistance.

[FR Doc. E7–21184 Filed 10–25–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–62,267]

Lamplight Farms, Menomonee Falls, WI; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on October 9, 2007 in response to a petition filed by a company official on behalf of workers of Lamplight Farms, Menomonee Falls, Wisconsin.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 18th day of October 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–21190 Filed 10–25–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–62,253]

Manpower Incorporated, Loveland, CO; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on October 4, 2007 in response to a petition filed by a company official on behalf of workers of Manpower Incorporated, Spring Lake, Michigan.

All workers of the subject firm are covered by a certification of eligibility to apply for worker adjustment assistance and alternative trade adjustment assistance under petition number TA–W–61,530 (amended), that does not expire until August 23, 2009.

Consequently, further investigation in this case would serve no purpose and the investigation under this petition has been terminated.

Signed at Washington, DC, this 22nd day of October 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–21189 Filed 10–25–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,983]

Molon Motor and Coil Corporation, El Paso, TX; Notice of Negative Determination Regarding Application for Reconsideration

By application dated September 17, 2007, the petitioner requested administrative reconsideration of the Department's negative determination regarding eligibility to apply for Trade Adjustment Assistance (TAA), applicable to workers and former workers of the subject firm. The denial notice was signed on September 7, 2007 and published in the **Federal Register** on September 21, 2007 (72 FR 54076).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) if it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) if in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The petition for the workers of Molon Motor and Coil Corporation, El Paso, Texas engaged in production of vacuum cleaner motors was denied because the ''contributed importantly'' group eligibility requirement of Section 222 of the Trade Act of 1974, as amended, was not met. The ''contributed importantly'' test is generally demonstrated through a

survey of the workers' firm's declining customers. The investigation revealed that all vacuum cleaner motors produced by the subject firm were exported to Mexico and the subject firm had no domestic customers. The investigation further revealed that there was no shift in production from that firm to a foreign country nor did the subject firm import vacuum cleaner motors in 2005, 2006 and January through July 2007.

The petitioner attached a letter from the subject firm's customer indicating that this customer ''discontinued use of the Molon motors in favor of an Asian sourced motor'' and that this customer ''was the sole customer using the motors produced'' at the subject firm.

The Department contacted the sole customer of the subject firm for further clarification. The customer confirmed that even though his firm is a U.S. based company, the production facility for which the vacuum cleaner motors were purchased is located in Mexico. The customer stated that all vacuum cleaner motors purchased from the subject firm were shipped directly to the Mexican facility and thus were exports. This facility in Mexico is now purchasing vacuum cleaner motors from Asia and there was no increase in imports of vacuum cleaner motors into the United States by this customer. Therefore, the loss of business at the subject firm is attributed to a loss in export sales.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed in Washington, DC, this 19th day of October, 2007.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–21187 Filed 10–25–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,555]

National Braid Manufacturing Co., Also Known As Long Island City Trim, Long Island City, NY; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on June 15, 2007, applicable to workers of National Braid Manufacturing Co., Long Island City, New York. The notice was published in the **Federal Register** on June 28, 2007 (72 FR 35516).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of trimmings for textiles.

New information shows that the correct name of the subject firm should read National Braid Manufacturing Co., also known as Long Island City Trim. Workers separated from employment at the subject firm had their wages reported under a separate unemployment insurance (UI) tax accounts for National Braid Manufacturing Co., also known as Long Island City Trim.

Accordingly, the Department is amending this certification to correctly identify the name of the subject firm.

The intent of the Department's certification is to include all workers of National Braid Manufacturing Co., Long Island City, New York, who were adversely affected by increased company imports of trimmings for textiles.

The amended notice applicable to TA–W–61,555 is hereby issued as follows:

''All workers of National Braid Manufacturing Co., also known as Long Island City Trim, Long Island City, New York, who became totally or partially separated from employment on or after May 15, 2006, through June 15, 2009, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.''

Signed at Washington, DC this 23rd day of October 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–21186 Filed 10–25–07; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Application Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received under the Antarctic Conservation Act.

SUMMARY: Notice is hereby given that the National Science Foundation (NSF) has received a waste management permit application for operation of a remote field support and emergency provisions helicopter flight seeing for the Motor Vessel, *Octopus* for the 2006–2007 austral summer season. The application is submitted to NSF pursuant to regulations issued under the Antarctic Conservation Act of 1978.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by November 26, 2007. Permit applications may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Dr. Polly A. Penhale, Environmental Officer, at the above address or (703) 292–8030.

SUPPLEMENTARY INFORMATION: NSF's Antarctic Waste Regulation, 45 CFR part 671, requires all U.S. citizens and entities to obtain a permit for the use or release of a designated pollutant in Antarctica, and for the release of waste in Antarctica. NSF has received a permit application under this Regulation for a team of eight traveling with the *S/V Pelagic Australis* that will spend four weeks traveling by sailboat, sea kayak, and foot along the northeastern coast of the Antarctic Peninsula and certain outlying islands. Some camping ashore will occur and any and all trash generated will be returned to the *Pelagic* for disposal in accordance with the vessel's permitted procedures. Fuel for cook stoves will be transferred to appropriate fuel bottles prior to leaving South America. Any batteries taken

ashore will be removed and non-rechargeable batteries will be returned to South America for disposal. Conditions of the permit would include requirements to report on the removal of materials and any accidental releases, and management of all waste, including human waste, in accordance with Antarctic waste regulations.

Application for the permit is made by: Jon S. Bowermaster, OCEANS 8 Productions, Box 730, Stone Ridge, NY 12484.

Location: Antarctic Peninsula.

Dates: December 1, 2007 to January 30, 2008.

Nadene G. Kennedy,

Permit Officer.

[FR Doc. E7–21176 Filed 10–25–07; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Panel for Integrative Activities; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463 as amended), the National Science Foundation announces the following meeting:

Name: Advisory Panel for Integrative Activities (#1373).

Dates & Times: November 14, 2007—1 p.m.–5:30 p.m.; November 15, 2007—8 a.m.–4:30 p.m.; November 16, 2003—7:30 a.m.–12:30 p.m.

Places:

Hilton Arlington Hotel, 950 North Stafford Street, Arlington, Virginia.

Science and Technology Policy Institute (STPI), 1899 Pennsylvania Ave, NW., Washington, DC.

Office of Science and Technology Policy (OSTP), Old Executive Office Building, Washington, DC.

Type of Meeting: Part-Open.

Contact Person: Connie Della-Piana, PhD. Office of Integrative Activities, Office of the Director, Room 1270, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: 703/292–8040.

Purpose of Meeting: To provide advice and recommendations concerning the use of and need for the Science and Technology Policy Institute.

Agenda

Wednesday, November 14, 2007

1 p.m.–4 p.m. Hilton Arlington Hotel. Open—Overview and history of Federally Funded Research and Development Center (FFRDC); Briefings and Panel Discussions.

4:30 p.m.–5:30 p.m. Hilton Arlington, Hotel. Closed—Review of contract.

Thursday, November 15, 2007

8 a.m.–9 p.m. Hilton Arlington Hotel. Open—Briefings and Panel Discussions with Deputy Director, NSF.

9:30 a.m.–12n Science and Technology Policy Institute. Open—Presentations and briefing by STPI.

12n–2 p.m. Science and Technology Policy Institute. Closed—Review and evaluation of the use and need for the Institute.

2:30 p.m.–4:30 p.m. Office of Science and Technology Policy. Closed—Briefings and discussions with OSTP representatives.

Friday, November 16, 2007

8 a.m.–1:30 p.m. Hilton Arlington Hotel. Closed—Meetings with NSF representatives and other government clients. Review and prepare report.

Reason for Closing: The contract being reviewed includes information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the contract. Discussions will include the development of negotiating and implementing strategies. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) and (9)(B) of the Government in the Sunshine Act.

Dated: October 23, 2007.

Susanne Bolton,

Committee Management Officer.

[FR Doc. E7–21164 Filed 10–25–07; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–10346; License No. 50–16084–01; EA–07–261]

In the Matter of Alaska Industrial X-Ray, Inc., Anchorage, AK; Order Suspending Licensed Activities (Effective Immediately)

I

Alaska Industrial X-Ray, Inc., (AIX or Licensee) is the holder of NRC License No. 50–16084–01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 34. The license authorizes the Licensee to conduct industrial radiography at temporary job sites anywhere in the United States where the NRC maintains jurisdiction for regulating licensed material. The license was issued on October 24, 1990, was most recently renewed on March 13, 2001, and is due to expire on March 31, 2011.

II

On June 4, 2007, the NRC's Office of Investigation (OI) initiated an investigation into AIX's activities at a facility, not owned by AIX, located in Anchorage, Alaska. This off-site facility is owned by an AIX client, and AIX has been performing radiography at that location since the 1990s. Based on information obtained during the investigation, serious concerns were identified concerning the AIX senior managers' oversight of licensed activities and AIX's ability to protect the public health and safety. Specifically, AIX radiographers, including the company Radiation Safety Officer, knowingly conducted radiography activities without the two individuals required by 10 CFR 34.41(a) (sometimes called the 2-person rule). This occurred on numerous instances over a period of up to three years and presented unnecessary risk to the public health and safety.

In the 1990s, AIX constructed a facility that was referred to as a ''vault'' at its client's facility. AIX applied to the NRC to have the ''vault'' approved as a Permanent Radiographic Installation as described in 10 CFR 34.33. Radiography conducted in an authorized permanent radiographic installation could be conducted with a single radiographer; otherwise, 10 CFR 34.41(a) requires, in part, that at least two qualified individuals be present during radiography. However, the NRC never approved the ''vault'' as a Permanent Radiographic Installation because of serious deficiencies in the design and requested further information from AIX. One of the design deficiencies was that the ''vault'' had very little shielding on most of the front of the vault; the shielding consisted of a lead-lined steel frame gate that was only about 3½ feet tall and an industrial tarp that was pulled across the front. As such, AIX estimated radiation exposures 20 feet in front of the ''vault'' exceeded many hundred times the NRC's 2 mR/hr limit. In addition, the NRC believes there was access to the roof of the facility, which was made of ¾ inch plywood (very limited shielding material), resulting in dose rates in excess of the NRC's 2 mR/hr limit. The licensing action was closed in 2002 after AIX did not make the structural changes necessary to obtain approval.

The investigation revealed that on numerous occasions over a period of up to three years, AIX would send two qualified individuals to the off-site facility to perform radiography, and that AIX would commence radiography in compliance with 10 CFR 34.41(a).

However, AIX radiographers, including the company radiation safety officer, admitted that eventually, one individual would return to the company's shop (located several miles away) to develop film; while the remaining radiographer continued with radiography operations, without the second qualified individual, unnecessarily endangering the public health and safety. In addition, one radiographer admitted to performing radiography activities without the second qualified individual, at a second facility owned by the licensee, several times over the past year, also in violation of 10 CFR 34.41(a). The company president stated he had ''an inkling of what was going on'' and that he ''suspected it.'' All individuals interviewed justified the violation due to the additional safeguards that had been installed at the ''vault'' which AIX had attempted to gain NRC approval as a Permanent Radiographic Installation. However, as noted above, the ''vault'' was not approved by the NRC and was therefore not adequate to ensure the protection of the public health and safety; without NRC approval of this facility the licensee is required to follow 10 CFR 34.41(a). Use of two qualified persons observing radiographic operations provides a high level of assurance that members of the public will be prevented from entering the restricted area during those operations and risk receiving radiation exposure well in excess of regulatory limits. Also, the requirement of two individuals can further protect against high doses to either of the qualified persons in circumstances whereby one of them becomes incapacitated during radiographic source exposure.

The NRC notes that enforcement action was taken against AIX on April 25, 2001 (EA–01–015) for a willful failure to follow 10 CFR 34.41(a), while conducting radiography at the same off-site facility. During an OI investigation in 2000, a radiographer admitted he did not always follow the 2-person rule on limited occasions at this same ''vault'' that AIX had constructed. At the time of the predecisional enforcement conference, AIX was trying to get the ''vault'' approved as a Permanent Radiographic Installation. The company president and the company radiation safety officer attended the predecisional enforcement conference with AIX on March 13, 2001. A central issue was that the ''vault'' was not approved as a permanent radiographic installation, and so the radiographer's actions were in violation of 10 CFR 34.41(a). The NRC's April 25, 2001, letter also made this point, and a Notice of Violation was issued to AIX for the violation of 10 CFR 34.41(a). AIX's corrective actions were provided by letters dated February 25, 2001, and March 12, 2001.

The NRC is continuing its review of the information obtained through the investigation. However, based on the information gathered thus far, the NRC has serious concerns about the potential safety consequences inherent in not complying with regulatory requirements during radiography activities. Such activities are among the most risk-significant activities conducted by material licensees and, in the absence of appropriate controls, may lead to significant radiation exposures to individuals. The deficiencies in the design of the ''vault'' raised numerous questions and did not meet NRC requirements for designation as a Permanent Radiographic Installation. As such, the NRC is concerned that a member of the public could unknowingly be exposed as a result of AIX's failures to follow the 2-person rule. In addition, the NRC has found that AIX radiographers, including the radiation safety officer, have violated 10 CFR 34.41(a) on numerous instances for a period of up to three years, and that the company president, who at a minimum suspected violations were occurring, did not take appropriate actions to stop them. In addition, the NRC had previously issued an escalated enforcement action to AIX for a willful violation of the same regulation at the same location. This conduct undermines the trust the NRC had placed in AIX's senior officials.

III

Consequently, in light of the above, I lack the requisite reasonable assurance that the Licensee's current operations can be conducted under License No. 50–16084–01 in compliance with the Commission's requirements and that the health and safety of the public, including the Licensee's employees, will be protected. Therefore, the public, health, safety and interest require that License No. 50–16084–01 be suspended in part and that licensed material be placed in locked, safe storage, pending further review of the information in this case. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the violation and conduct described above is such that the public health, safety and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to Sections 81, 161b, 161i, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR part 34, *it is hereby ordered, effective immediately, that:*

A. The authority to perform radiographic operations under License No. 50–16084–01 is hereby suspended pending further notice by the NRC. The Licensee shall cease all radiographic operations and return all byproduct material possessed under this license to locked, safe storage at the Licensee's facilities. All other requirements of the License and applicable Commission requirements, including those in 10 CFR part 20 remain in effect.

B. Within 24 hours following issuance of this Order, the Licensee shall contact Mr. Leonard Wert, Director, Division of Nuclear Materials Safety, NRC Region IV, or his designee, through the NRC Operations Center at telephone number (301) 816–5100, and advise him of the current location, physical status, and storage arrangements of licensed material. A written response documenting this information shall be submitted, under oath or affirmation, to the Regional Administrator, U.S. NRC Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011 within seven days of the date of this Order.

C. If the Licensee removes licensed material from locked storage, the Licensee shall notify NRC Region IV no less than 48 hours before removal of the licensed material. This notice shall be provided to Mr. Leonard Wert, Director, Division of Nuclear Materials Safety, or his designee, at telephone number (817) 860–8106.

D. The Licensee shall not receive any NRC-licensed material while this Order is in effect.

E. All records related to licensed activities shall be maintained in their current form and must not be altered in any way.

F. Within 60 days of the date of this Order, the Licensee shall provide, in writing, specific actions that are acceptable to the NRC and that provide adequate assurance by independent means that the Licensee, if it conducts radiography activities, will comply with NRC regulations.

The Regional Administrator, Region IV, may, in writing, relax or rescind this order upon demonstration by the Licensee of good cause.

V

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order within 20 days of its issuance. In addition, the Licensee and any other person adversely affected by this Order may request a hearing on this Order within 20 days of its issuance. Where good cause is

shown, consideration will be given to extending the time to answer or request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, and include a statement of good cause for the extension.

A request for a hearing must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in August, 2007, 72 FR 49,139 (Aug. 28, 2007). The E-Filing process requires participants to submit and serve documents over the Internet or, in some cases, to mail copies on electronic optical storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements associated with E-Filing, at least five (5) days prior to the filing deadline the requestor must contact the Office of the Secretary by e-mail at *HEARINGDOCKET@NRC.GOV*, or by calling (301) 415–1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any NRC proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances when the requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at *http://www.nrc.gov/site-help/e-submittals/install-viewer.html*. Information about applying for a digital ID certificate also is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html*.

Once a requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for a hearing through EIE. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the filer submits its document through EIE. To be timely, electronic filings must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, any others who wish to participate in the proceeding (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request is filed so that they may obtain access to the document via the E-Filing system.

A person filing electronically may seek assistance through the ''Contact Us'' link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html* or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397–4209 or locally, (301) 415–4737.

Participants who believe that they have good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville, Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd.nrc.gov/EHD_Proceeding/home.asp*, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, Participants are requested not to include copyrighted materials in their works.

If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d).

If a hearing is requested by a Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained. Pursuant to 10 CFR 2.202(c)(2)(i), the Licensee, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error. In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received. *An answer or a request for hearing shall not stay the immediate effectiveness of this order.*

For the Nuclear Regulatory Commission.

Dated this 19th day of October, 2007.

Martin J. Virgilio,

Deputy Executive Director for Materials, Waste, Research, State, Tribal, and Compliance Programs and Compliance Programs, Office of the Executive Director for Operations.

[FR Doc. E7–21117 Filed 10–25–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–334 and 50–412]

FirstEnergy Nuclear Operating Company; Beaver Valley Power Station, Units 1 and 2; Notice of Acceptance for Docketing of the Application and Notice of Opportunity for Hearing Regarding Renewal of Facility Operating License Nos. DPR–66 and NPF–73 for an Additional 20-Year Period

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering an application for the renewal of Operating License Nos. DPR–66 and NPF–73, which authorize FirstEnergy Nuclear Operating Company (FENOC), to operate Beaver Valley Power Station, Units 1 and 2, respectively, at 2900 megawatts thermal for each unit. The renewed licenses would authorize the applicant to operate Beaver Valley Power Station, Units 1 and 2, for an additional 20 years beyond the period specified in the current licenses. The current operating licenses for Beaver Valley Power Station, Units 1 and 2, expire on January 29, 2016, and May 27, 2026, respectively.

FENOC submitted the application dated August 27, 2007, pursuant to Title 10 of the *Code of Federal Regulations* CFR part 54 (10 CFR part 54), to renew Operating License Nos. DPR–66 and NPF–73 for Beaver Valley Power Station, Units 1 and 2, respectively. A Notice of Receipt and Availability of the license renewal application (LRA) was published in the **Federal Register** on September 24, 2007 (72 FR 54301).

The Commission's staff has determined that FENOC has submitted sufficient information in accordance with 10 CFR 54.19, 54.21, 54.22, 54.23, 51.45, and 51.53(c) to enable the staff to undertake a review of the application, and the application is therefore acceptable for docketing. The current Docket Nos. 50–334 and 50–412 for Operating License Nos. DPR–66 and NPF–73, respectively, will be retained. The determination to accept the license renewal application for docketing does not constitute a determination that a renewed license should be issued, and does not preclude the NRC staff from requesting additional information as the review proceeds.

Before issuance of each requested renewed license, the NRC will have made the findings required by the Atomic Energy Act of 1954 (the Act), as amended, and the Commission's rules and regulations. In accordance with 10 CFR 54.29, the NRC may issue a renewed license on the basis of its review if it finds that actions have been identified and have been or will be taken with respect to: (1) Managing the effects of aging during the period of extended operation on the functionality of structures and components that have been identified as requiring aging management review; and (2) time-limited aging analyses that have been identified as requiring review, such that there is reasonable assurance that the activities authorized by the renewed license will continue to be conducted in accordance with the current licensing basis (CLB), and that any changes made to the plant's CLB comply with the Act and the Commission's regulations.

Additionally, in accordance with 10 CFR 51.95(c), the NRC will prepare an environmental impact statement that is a supplement to the Commission's NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Power Plants,'' dated May 1996. In considering the LRA, the Commission must find that the applicable requirements of Subpart A of 10 CFR part 51 have been satisfied. Pursuant to 10 CFR 51.26, and as part of the environmental scoping process, the staff intends to hold a public scoping meeting. Detailed information regarding the environmental scoping meeting will be the subject of a separate **Federal Register** notice.

Within 60 days after the date of publication of this **Federal Register** Notice, any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing or a petition for leave to intervene with respect to the renewal of the license. Requests for a hearing or petitions for leave to intervene must be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852 and is accessible from the NRC's Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC's PDR reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by e-mail at *pdr@nrc.gov.* If a request for a hearing/petition for leave to intervene is filed within the 60-day period, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel will issue a notice of a hearing or an appropriate order. In the event that no request for a hearing or petition for leave to intervene is filed within the 60-day period, the NRC may, upon completion of its evaluations and upon making the findings required under 10 CFR parts 51 and 54, renew the license without further notice.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding, taking into consideration the limited scope of matters that may be considered pursuant to 10 CFR parts 51 and 54. The petition must specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the petitioner/requestor seeks to have litigated in the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases of each contention and a concise statement of the alleged facts or the expert opinion that supports the contention on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the requestor/petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The requestor/petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact.[1] Contentions shall be limited to

[1] To the extent that the application contains attachments and supporting documents that are not

matters within the scope of the action under consideration. The contention must be one that, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

The Commission requests that each contention be given a separate numeric or alpha designation within one of the following groups: (1) Technical (primarily related to safety concerns); (2) environmental; or (3) miscellaneous.

As specified in 10 CFR 2.309, if two or more requestors/petitioners seek to co-sponsor a contention or propose substantially the same contention, the requestors/petitioners will be required to jointly designate a representative who shall have the authority to act for the requestors/petitioners with respect to that contention.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing. A request for hearing or a petition for leave to intervene must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in August 2007, 72 FR 49, 139 (August 28, 2007). The E-filing process requires participants to submit and serve documents over the internet or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least five (5) days prior to the filing deadline, the petitioner/requestor must contact the Office of the Secretary by e-mail at *HEARINGDOCKET@NRC.GOV*, or by calling (301) 415–1677, to request: (1) A digital ID certificate, which allows the participant (or the counsel or representative) to digital sign documents and access the E-Submittal server for any proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances in which the requestor/petitioner (or it's council or representative) already holds an NRC-issued digital ID certificate). Each requestor/petitioner will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at *http://www.nrc.gov/site-help/e-submittals/install-viewer.html*. Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html*.

Once a requestor/petitioner has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html*. A filing is considered complete at the time the filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representatives) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically may seek assistance through the ''Contact Us'' link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html* or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397–4209 or locally, (301) 415–4737.

Participants who believe that they have a good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudication Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail or expedited delivery service upon depositing the document with the provider of the service.

Non-timely requests and/or petitions and contentions will not be entertained absent a determination by the Commission, the presiding officer, or the Atomic Safety and Licensing Board Panel that the petition and/or request should be granted and/or the contentions should be admitted based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii). To be timely, filings must be submitted no later than 11:59 p.m. Eastern Time on the due date.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd.nrc.gov/EHD_Proceeding/home.asp*, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board Panel, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Detailed information about the license renewal process can be found under the Nuclear Reactors icon at *http://www.nrc.gov/reactors/operating/licensing/renewal.html* on the NRC's Web site. Copies of the application to renew the operating licenses for Beaver Valley Power Station, Units 1 and 2, are available for public inspection at the Commission's PDR, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852–2738, and at *http://www.nrc.gov/reactors/operating/licensing/renewal/applications.html*, the NRC's Web site while the application is under review. The application may be accessed in ADAMS through the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm/adams.html* under ADAMS Accession Number ML072430913. As stated above, persons who do not have access to ADAMS or who encounter problems in

publicly available because they are asserted to contain safeguards or proprietary information, petitioners desiring access to this information should contact the applicant or applicant's counsel to discuss the need for a protective order.

accessing the documents located in ADAMS may contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by e-mail to *pdr@nrc.gov*.

The NRC staff has verified that a copy of the LRA is also available to local residents near Beaver Valley Power Station, Units 1 and 2, at the Beaver Area Memorial Library, 100 College Avenue, Beaver, Pennsylvania 15009, and the Beaver County Library System, 1 Campus Drive, Monaca, Pennsylvania 15061.

Dated at Rockville, Maryland, this 22nd day of October, 2007.

For the Nuclear Regulatory Commission.

Louise Lund,

Acting Director, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. E7–21086 Filed 10–25–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ESBWR Subcommittee; Notice of Meeting

The ACRS Subcommittee on ESBWR will hold a meeting on November 15, 2007, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed to discuss unclassified safeguards and proprietary information pursuant to 5 U.S.C. 552b(c)(3) and (4).

The agenda for the subject meeting shall be as follows:

Thursday, November 15, 2007—8:30 a.m. until the conclusion of business.

The Subcommittee will review and discuss the Draft Safety Evaluation with Open Items for several chapters of the ESBWR Design Certification and make a recommendation to the full Committee. The Subcommittee will hear presentations by and hold discussions with representatives of the NRC staff, GE-Hitachi Nuclear Energy Americas LLC, and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Officer, Mr. Charles G. Hammer (telephone 301/415–7363) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on September 26, 2007 (72 FR 54695).

Further information regarding this meeting can be obtained by contacting the Designated Federal Officer between 6:45 a.m. and 3:30 p.m. (ET). Persons planning to attend this meeting are urged to contact the above named individual at least two working days prior to the meeting to be advised of any potential changes to the agenda.

Dated: October 23, 2007.

Cayetano Santos,

Chief, Reactor Safety Branch.

[FR Doc. 07–5335 Filed 10–24–07; 10:24 am]

BILLING CODE 7590–01–P

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review, Request for Comments

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Railroad Retirement Board (RRB) is forwarding an Information Collection Request (ICR) to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB) to request a revision to a currently approved collection of information: 3220–0022, Application and Claim for Unemployment Benefits and Employment Service consisting of Form(s) UI–1 and UI–1 (Internet), Application for Unemployment Benefits and Employment Service, and UI–3 and UI–3 (Internet), Claim for Unemployment Benefits. Our ICR describes the information we seek to collect from the public. Review and approval by OIRA ensures that we impose appropriate paperwork burdens.

The RRB invites comments on the proposed collection of information to determine (1) the practical utility of the collection; (2) the accuracy of the estimated burden of the collection; (3) ways to enhance the quality, utility and clarity of the information that is the subject of collection; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology. Comments to RRB or OIRA must contain the OMB control number of the ICR. For proper consideration of your comments, it is best if RRB and OIRA receive them within 30 days of publication date.

Section 2 of the Railroad Unemployment Insurance Act (RUIA), provides unemployment benefits for qualified railroad employees. These benefits are generally payable for each day of unemployment in excess of four during a registration period (normally a period of 14 days).

Section 12 of the RUIA provides that the RRB establish, maintain and operate free employment facilities directed toward the reemployment of railroad employees. The procedures for applying for the unemployment benefits and employment service and for registering and claiming the benefits are prescribed in 20 CFR part 325.

Form UI–1 (or its Internet equivalent, Form UI–1 (Internet)), *Application for Unemployment Benefits and Employment Service*, is completed by a claimant for unemployment benefits once in a benefit year, at the time of first registration. Completion of Form UI–1 or UI–1 (Internet) also registers an unemployment claimant for the RRB's employment service. The RRB also utilizes Form UI–3, (or its Internet equivalent Form UI–3 (Internet)) *Claim for Unemployment Benefits* for use in claiming unemployment benefits for days of unemployment in a particular registration period, normally a period of 14 days.

Completion of Forms UI–1, UI–1(Internet), UI–3 and UI–3 (Internet) is required to obtain or retain benefits. The number of responses required of each claimant varies, depending on their period of unemployment.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (72 FR 47085–86 on August 22, 2007) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Application and Claim for Unemployment Benefits and Employment Service.

OMB Control Number: 3220–0022.

Form(s) submitted: UI–1, UI–1 (Internet), UI–3, UI–3 (Internet).

Type of request: Revision of a currently approved collection.

Affected public: Individuals or households.

Abstract: Under Section 2 of the Railroad Unemployment Insurance Act, unemployment benefits are provided for qualified railroad employees. The collection obtains the information needed for determining the eligibility to and amount of such benefits from railroad employees.

Changes Proposed: The RRB proposes no changes to Form(s) UI–1, UI–1 (Internet), UI–3, and UI–3 (Internet).

The burden estimate for the ICR is as follows:

Estimated Completion Time for Form(s): Completion time for Form UI–1 and UI–1 (Internet) is estimated at 10 minutes. Completion time for Form UI–3 and UI–3 (Internet) is estimated at 6 minutes.

Estimated annual number of respondents: 9,977.

Total annual responses: 84,303.

Total annual reporting hours: 9,096.

Additional Information or Comments: Copies of the forms and supporting documents can be obtained from Charles Mierzwa, the agency clearance officer (312–751–3363) or *Charles.Mierzwa@rrb.gov*.

Comments regarding the information collection should be sent to Ronald J. Hodapp, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or *Ronald.Hodapp@RRB.GOV*, and to the Office of Management Budget at ATTN: Desk Officer for RRB, Fax: (202) 395–6974 or via E-mail to: *OIRA_Submission@omb.eop.gov*.

Charles Mierzwa,

Clearance Officer.

[FR Doc. E7–21076 Filed 10–25–07; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56682; File No. SR–FINRA–2007–013]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to NASD Rule 3210 in Light of Amendments to the SEC Regulation SHO Delivery Requirements

October 22, 2007.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 12, 2007, Financial Industry Regulatory Authority, Inc. (''FINRA'') (f/k/a National Association of Securities Dealers, Inc. (''NASD'')) 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 substantially by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend NASD Rule 3210 (Short Sale Delivery Requirements) in light of the amendments to Rule 203 of Regulation SHO under the Act.[4]

Below is the text of the proposed rule change. Proposed new language is *italicized;* proposed deletions are in [brackets].

* * * * *

3210. Short Sale Delivery Requirements

(a) If a participant of a registered clearing agency has a fail to deliver position at a registered clearing agency in a non-reporting threshold security for 13 consecutive settlement days, the participant shall immediately thereafter close out the fail to deliver position by purchasing securities of like kind and quantity.

(1) Provided, however, a participant of a registered clearing agency that has a fail to deliver position at a registered clearing agency in a non-reporting threshold security on October 15, 2007, and which, prior to October 15, 2007, had been previously grandfathered from the close-out requirement in paragraph (a) (i.e., because the participant of a registered clearing agency had the fail to deliver position at a registered clearing agency on the settlement day preceding the day that the security became a non-reporting threshold security), shall close out that fail to deliver position within thirty-five settlement days of October 15, 2007 by purchasing securities of like kind and quantity. The requirements in paragraph (b) shall apply to all such fails to deliver that are not closed out in conformance with this paragraph (a)(1).

(2) Provided, however, if a participant of a registered clearing agency has a fail to deliver position at a registered clearing agency for thirty-five consecutive settlement days in a non-reporting threshold security that was sold pursuant to SEC Rule 144, the participant shall immediately thereafter close out the fail to deliver position in the security by purchasing securities of like kind and quantity. The requirements in paragraph (b) shall apply to all such fails to deliver that are not closed out in conformance with this paragraph (a)(2).

[(b) The provisions of this rule shall not apply to the amount of the fail to deliver position that the participant of a registered clearing agency had at a registered clearing agency on the settlement day immediately preceding the day that the security became a non-reporting threshold security; provided, however, that if the fail to deliver position at the clearing agency is subsequently reduced below the fail to deliver position on the settlement day immediately preceding the day that the security became a non-reporting threshold security, then the fail to deliver position excepted by this paragraph (b) shall be the lesser amount.]

(b)[(c)] If a participant of a registered clearing agency has a fail to deliver position at a registered clearing agency in a non-reporting threshold security for 13 consecutive settlement days (*or 35 consecutive settlement days if entitled to rely on paragraphs (a)(1) or (a)(2) of this rule*), the participant and any broker or dealer for which it clears transactions, including any market maker that would otherwise be entitled to rely on the exception provided in paragraph (b)(2)(iii) of SEC Rule 203 of Regulation SHO, may not accept a short sale order in the non-reporting threshold security from another person, or effect a short sale in the non-reporting threshold security for its own account, without borrowing the security or entering into a bona-fide arrangement to borrow the security, until the participant closes out the fail to deliver position by purchasing securities of like kind and quantity.

(c)[(d)] If a participant of a registered clearing agency reasonably allocates a portion of a fail to deliver position to another registered broker or dealer for which it clears trades or for which it is responsible for settlement, based on such broker or dealer's short position, then the provisions of this rule relating to such fail to deliver position shall apply to the portion of such registered broker or dealer that was allocated the fail to deliver position, and not to the participant.

(d)[(e)] A participant of a registered clearing agency shall not be deemed to have fulfilled the requirements of this rule where the participant enters into an arrangement with another person to purchase securities as required by this rule, and the participant knows or has reason to know that the other person will not deliver securities in settlement of the purchase.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] *See* Securities Exchange Act Release No. 56212 (August 7, 2007), 72 FR 45543 (August 14, 2007).

(e)[(f)] For the purposes of this rule, the following terms shall have the meanings below:

(1) The term ''market maker'' has the same meaning as in section 3(a)(38) of the Exchange Act.

(2) The term ''non-reporting threshold security'' means any equity security of an issuer that is not registered pursuant to section 12 of the Exchange Act and for which the issuer is not required to file reports pursuant to section 15(d) of the Exchange Act:

(A) For which there is an aggregate fail to deliver position for five consecutive settlement days at a registered clearing agency of 10,000 shares or more and for which on each settlement day during the five consecutive settlement day period, the reported last sale during normal market hours for the security on that settlement day that would value the aggregate fail to deliver position at $50,000 or more, provided that if there is no reported last sale on a particular settlement day, then the price used to value the position on such settlement day would be the previously reported last sale; and

(B) Is included on a list published by NASD.

A Security shall cease to be a non-reporting threshold security if the aggregate fail to deliver position at a registered clearing agency does not meet or exceed either of the threshold tests specified in paragraph *(e)*[(f)](2)(A) of this rule for five consecutive settlement days.

(3) The term ''participant'' means a participant as defined in section 3(a)(24) of the Exchange Act, that is an NASD member.

(4) The term ''registered clearing agency'' means a clearing agency, as defined in section 3(a)(23)(A) of the Exchange Act, that is registered with the Commission pursuant to section 17A of the Exchange Act.

(5) The term ''settlement day'' means any business day on which deliveries of securities and payments of money may be made through the facilities of a registered clearing agency.

(f)[(g)] Pursuant to the Rule 9600 Series, the staff, for good cause shown after taking into consideration all relevant factors, may grant an exemption from the provisions of this rule, either unconditionally or on specified terms and conditions, to any transaction or class of transactions, or to any security or class of securities, or to any person or class of persons, if such exemption is consistent with the protection of investors and the public interest.

* * * * *

9610. Application

(a) Where to File

A member seeking exemptive relief as permitted under Rules 1021, 1050, 1070, 2210, 2315, 2320, 2340, 2520, 2710, 2720, 2790, 2810, 2850, 2851, 2860, Interpretive Material 2860–1, 3010(b)(2), 3020, 3150, *3210*, 3230, 5150, 6958, 8211, 8213, 11870, or 11900, or Municipal Securities Rulemaking Board Rule G–37 shall file a written application with the appropriate department or staff of NASD and provide a copy of the application to the Office of General Counsel of NASD.

(b) through (c) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 7, 2007, the SEC adopted certain amendments to Regulation SHO under the Act.[5] The SEC amended, among other things, the close-out requirement contained in Rule 203 of Regulation SHO to eliminate the ''grandfather'' [6] provision and extend the close-out requirement from 13 to 35 consecutive settlement days for fails to deliver resulting from sales of threshold securities pursuant to Rule 144 of the Securities Act of 1933.[7] The amendments to the close-out requirement in Rule 203 of Regulation SHO became effective on October 15, 2007.

The purpose of this proposed rule change is to make conforming changes to NASD Rule 3210 to reflect the amendments to Rule 203 of Regulation SHO by eliminating the grandfather provision from Rule 3210 and extending the close-out requirement for fails to deliver resulting from sales of non-reporting threshold securities pursuant to SEC Rule 144.

Proposed Amendments to NASD Rule 3210

NASD Rule 3210 (Short Sale Delivery Requirements) applies delivery requirements to non-reporting threshold securities that are substantially similar to the Regulation SHO delivery requirements, which apply only to reporting securities.[8] In the original rule change (SR–NASD–2004–044) proposing Rule 3210, FINRA indicated that it intended to apply and interpret the requirements of Rule 3210 consistent with the SEC's application and interpretation of Regulation SHO, and to the extent there were subsequent amendments to Regulation SHO, FINRA would consider amending its requirements accordingly.

Given the SEC's recent amendments to the Regulation SHO close-out requirement, FINRA is proposing to amend Rule 3210 to make conforming amendments to its mandatory close-out requirement to eliminate the grandfathering provision and extend the close-out requirement for SEC Rule 144 restricted securities. Specifically, consistent with the SEC's amendments to Rule 203(b)(3)(i) of Regulation SHO, FINRA is proposing (1) to require that any previously grandfathered fail to deliver position in a non-reporting security that is on the Rule 3210 threshold list on the October 15, 2007 operative date of the proposed rule change be closed out within 35 settlement days of such date; (2) that if the fail to deliver position has persisted for 35 consecutive settlement days from the October 15, 2007 operative date of the proposed rule change, the proposal would prohibit a participant and any broker-dealer for which it clears transactions, including market makers, from accepting any short sale orders or effecting further short sales in the particular non-reporting threshold security without borrowing, or entering

[5] *See id.*

[6] The ''grandfather'' provision excluded from the Regulation SHO close-out requirement fail to deliver positions that were established prior to the security becoming a threshold security or prior to the Regulation SHO effective date. Specifically, the grandfather provision applied to two situations: (1) Fail to deliver positions occurring before the January 3, 2005 Regulation SHO effective date; and (2) fail to deliver positions that were established on or after January 3, 2005, but prior to the security appearing on the Regulation SHO threshold securities list. *See* Securities Exchange Act Release No. 54154 (July 14, 2006), 71 FR 41710 (July 21, 2006). *See also* SEC Division of Market Regulation: Key Points About Regulation SHO, dated April 11, 2005.

[7] The SEC also adopted amendments to update the market decline limitation in Rule 200(e)(3) of Regulation SHO.

[8] The term ''reporting security'' means any equity security of an issuer that is registered under Section 12 of the Act or that is required to file reports under Section 15(d) of the Act.

into a bona-fide arrangement to borrow, the security until the participant closes out the entire fail to deliver position by purchasing securities of like kind and quantity; and (3) that if a security becomes a non-reporting threshold security after the October 15, 2007 operative date of the proposed rule change, any fails to deliver in that security that occurred prior to the security becoming a non-reporting threshold security would become subject to Rule 3210's mandatory 13 settlement day close-out requirement, similar to any other fail to deliver position in a non-reporting threshold security.

Likewise, in light of the SEC's recent amendments to provide additional time to close-out fails to deliver resulting from sales of threshold securities pursuant to SEC Rule 144, FINRA is proposing to amend Rule 3210 to make conforming amendments to its close-out requirement. Specifically, consistent with the SEC's amendments to Rule 203 of Regulation SHO, FINRA is proposing to amend Rule 3210 to extend the close-out requirement from 13 to 35 consecutive settlement days for fails to deliver resulting from sales of non-reporting threshold securities pursuant to SEC Rule 144. Also consistent with the SEC's amendments to the Regulation SHO close-out requirement, FINRA is proposing to apply the pre-borrow requirement in amended Rule 3210(b) to these fails to deliver. Therefore, if the fail to deliver position persists for 35 consecutive settlement days, a participant of a registered clearing agency and any broker-dealer for which it clears transactions, including market makers, would be prohibited from effecting further short sales in the particular non-reporting threshold security without borrowing, or entering into a bona-fide arrangement to borrow, the security until the participant closes out the entire fail to deliver position by purchasing securities of like kind and quantity.

FINRA believes that making conforming changes to Rule 3210 to maintain consistency with the Regulation SHO delivery requirements is appropriate. Further, as noted in the proposing and adopting releases relating to the amendments to Rule 203 of Regulation SHO, the SEC indicated that, if the proposed amendments to Regulation SHO were adopted, the SEC anticipated that Rule 3210 would be similarly amended.[9]

Lastly, as part of the rule change (SR–NASD–2004–044) proposing Rule 3210, the SEC approved paragraph (g) of Rule 3210, which permits FINRA to grant exemptive relief from the Rule 3210 short sale delivery requirements pursuant to the Rule 9600 Series. As part of another rule change, FINRA inadvertently deleted the reference to Rule 3210 in the list of rules in Rule 9610(a) for which exemptive relief may be available.[10] Accordingly, as part of this rule filing, FINRA proposes to amend Rule 9610(a) to re-insert the reference to Rule 3210.

Implementation

As noted above, FINRA has filed the proposed rule change for immediate effectiveness. FINRA proposes to make the proposed rule change operative on October 15, 2007, to coincide with the operative date of the amendments to Rule 203 of Regulation SHO.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act,[11] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change is necessary and appropriate to conform to the amendments to Rule 203 of Regulation SHO and to maintain consistent delivery requirements across securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2007–013 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2007–013. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be

[9] *See* Securities Exchange Act Release No. 54891 (December 7, 2006), 71 FR 75068 (December 13, 2006). *See also* Securities Exchange Act Release No. 56212 (August 7, 2007), 72 FR 45543 (August 14, 2007).

[10] *See* File SR–NASD–2005–087.

[11] 15 U.S.C. 78o–3(b)(6).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6).

available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–FINRA–2007–013 and should be submitted on or before November 16, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–21166 Filed 10–25–07; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56683; File No. SR–NASDAQ–2007–081]

Self-Regulatory Organizations; the NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 to Establish a New Service Called Nasdaq Regulation Reconnaissance Service (''Reg Recon'') To Assist Nasdaq Members in Their Efforts To Comply With Applicable Regulatory Requirements

October 22, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 26, 2007, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared substantially by Nasdaq. On October 15, 2007 Nasdaq filed Amendment No. 1 to the proposed rule change. Nasdaq filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to establish fees for a new real-time surveillance alert and report module to assist Nasdaq member firms with their Regulation NMS (''Reg NMS'') compliance. The text of the proposed rule change is available at http://www.nasdaq.complinet.com, the Exchange, and the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to establish a new service called Nasdaq Regulation Reconnaissance Service (''Reg Recon'') to assist Nasdaq members in their efforts to comply with applicable regulatory requirements. Specifically, Reg Recon will provide Nasdaq members with individualized real-time surveillance alerts of possible violations of Reg NMS under the Act. Members will also have access to download those surveillance alerts for use as part of their policies and procedures to ensure compliance with Reg NMS obligations. Reg Recon is intended as only one source of assistance for Nasdaq member firms with their Reg NMS compliance and does not purport in any way to ensure or guarantee Reg NMS compliance. Specifically, Reg Recon will be available as an add-on to the Nasdaq Workstation and Weblink ACT 2.0.

Section 12(f) of the Act[5] permits exchanges to extend ''unlisted trading privileges'' (''UTP'') to Nasdaq listed securities. Through UTP, other U.S. exchanges are able to quote and trade issues listed on Nasdaq. In addition, registered broker-dealers are permitted to execute transactions in the over-the-counter market and to report those trades to the Alternative Display Facility operated by the Financial Industry Regulatory Authority (''FINRA'') or to any of several Trade Reporting Facilities (''TRFs'') operated jointly by FINRA and one of several national securities exchanges. Under the UTP Plan, all U.S. exchanges that quote and trade Nasdaq listed securities must provide their data to a centralized securities information processor (''SIP'') for data consolidation and dissemination. Nasdaq, in its current role as the SIP for the UTP Plan, supports the UTP Quotation Data Feed (''UQDF'').[6]

Reg Recon will assist Nasdaq members in two ways. First, it will assist members with compliance with Rule 611 of Reg NMS by providing real-time alerts that are trade reported by the member to the FINRA/Nasdaq TRF and represent potential trade-throughs. Nasdaq will generate these alerts by reading the UQDF data feed and comparing it to the prices of trades reported to the TRF. When that comparison reveals that a potential trade-through has occurred, the Reg Recon functionality will send the member a real-time surveillance alert. Nasdaq expects that firms will use these alerts as part of their compliance procedures to verify that the TRF trade was properly executed and trade reported.

Second, Reg Recon will provide subscribers with Nasdaq Self Help Declarations/Revocations messages (''Notices''). These Notices will alert participants that Nasdaq is experiencing communications issues with a particular market center. It is intended to cause members to perform an independent review of their communications with that market center and assess their trading obligations with respect to that market. Nasdaq has stated that these Notices are not intended to relieve firms of their obligations to conduct independent self-help analysis and to adopt policies and procedures designed to achieve compliance with those obligations.

Both real-time surveillance alerts and the Notices will be available to download each day to allow firms to review their TRF trade reporting activities. The product also provides reports that give users the ability to generate and download reports to view all of their potential TRF trade-throughs and sort by exempt versus non-exempt, intermarket sweep order (''ISO'') versus non-ISO, and Nasdaq Self Help Declarations/Revocations. Additionally,

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] 15 U.S.C. 78l(f).

[6] UQDF provides best bid and offer quotes from the UTP participants, as well as the consolidated national best bid and offer quotes (''NBBOs'') for securities listed on Nasdaq.

the product gives firms an ability to view their TRF ISO and potential trade-through violations relative to the rest of the industry.

The fee for this product will be a $1,000/market maker participant identifier/month subscription fee, which Nasdaq believes fairly reflects the value of this product. Use of the Reg Recon Service is voluntary and available only to Nasdaq member firms and the subscription fees will be imposed on all purchasers equally. The proposed fees will cover the costs associated with establishing the service, responding to customer requests, configuring Nasdaq's systems, programming to user specifications, and administering the service, among other things. Large firms' order management systems are offering this product at a much higher price, but they have the ability to charge a significant amount more than Nasdaq since firms potentially will need to route to other market centers to comply with the rule and the order management system will have all order information for every market center, not just the TRF data.

The Service is responsive to the requests of market participants seeking to augment their order management systems' solutions, as well as provide a back-up to those solutions, and for smaller firms with less sophisticated trading systems/environments. Nasdaq believes that the product is reasonably priced in light of the amount of quote data that must be processed coupled with the support required to assist firms in understanding the product and, in turn, Reg NMS.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[7] in general, and with Section 6(b)(5) of the Act,[8] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Use of the Reg Recon Service is voluntary and is responsive to the requests of market participants seeking to augment their order management systems' solutions, as well as provide a back-up to those solutions, and for smaller firms with less sophisticated trading systems/environments.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10]

Normally, a proposed rule change filed under Rule 19b–4(f)(6) may not become operative prior to 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii)[11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay set forth in Rule 19b–4(f)(6)(iii) under the Act.[12] The Commission believes that the earlier operative date is consistent with the protection of investors and the public interest because the proposed rule change permits the Exchange to provide without further delay a voluntary service that responds to the requests of market participants seeking to augment their order management systems' solutions. For these reasons, the Commission designates the proposal to be operative upon filing with the Commission.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[14]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2007–081 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2007–081. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires that a self-regulatory organization submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission notes that Nasdaq has satisfied the five-day pre-filing notice requirement.

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] For purposes only of waiving the 30-day operative delay of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[14] For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change under Section 19(b)(3)(C) of the Act, the Commission considers the period to commence on October 15, 2007, the date on which Nasdaq filed Amendment No. 1. See 15 U.S.C. 78s(b)(3)(C).

provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2007–081 and should be submitted on or before November 16, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–21180 Filed 10–25–07; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56688; File No. SR–NYSE–2007–77]

Self-Regulatory Organizations; New York Stock Exchange LLC.; Notice of Filing of Proposed Rule Change, as Modified by Amendment Nos. 1, 2, and 3 Thereto, To Amend Listing Fees for Structured Products

October 23, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 24, 2007, the New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by the Exchange. On October 3, 2007, the Exchange filed Amendment No. 1 to the proposed rule change. On October 12, 2007, the Exchange filed Amendment No. 2 to the proposed rule change. On October 22, 2007, the Exchange filed Amendment No. 3 to the proposed rule change. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its listing fees for structured products included in its Listed Company Manual (''Manual''). The Exchange seeks to clarify when certain existing fees will apply to specific structured products and also proposes to create a new fee section (Section 902.09) that will apply a new lower fee schedule to securities listed pursuant to Sections 703.15 (Foreign Currency Warrants and Currency Index Warrants), 703.17 (Stock Index Warrants Listing Standards), and 703.22 (Equity Index-Linked Securities, Commodity-Linked Securities and Currency-Linked Securities and Currency-Linked Securities). Except as described below, the proposed revisions would apply retroactively as of October 3, 2007. The text of the proposed rule change is available at the Commission's Public Reference Room, at the Exchange, and at *http://www.nyse.com*.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change, and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

a. Listing Fee Schedule

The Exchange proposes to amend its listing fees for structured products. The Exchange seeks to clarify when certain existing fees will apply to specific structured products and also proposes to create a new fee section (Section 902.09) that will apply a new lower fee schedule to securities listed pursuant to Sections 703.15 (Foreign Currency Warrants and Currency Index Warrants), 703.17 (Stock Index Warrants Listing Standards) and 703.22 (Equity Index-Linked Securities, Commodity-Linked Securities and Currency-Linked Securities) of the Manual. The listing and annual fees set forth in Section 902.05 of the Manual relate to long-term structured products (*i.e.*, a term of more than seven years) listed pursuant to Section 703.18 (Contingent Value Rights), the equity criteria set out in Section 703.19 (Other Securities) and Section 703.21 (Equity-Linked Debt Securities), and traded on the equity floor of the Exchange. The Exchange is also amending Section 902.05 of the Manual to correct two cross-references, clarifying that: (i) Fees applicable to structured products listed under the debt criteria set out in Section 703.19 and traded on NYSE Bonds are set forth in Section 902.08 (Listings Fees for Debt Securities); and (ii) fees applicable to short-term structured products are set forth in Section 902.06. The proposed revisions would apply retroactively as of October 3, 2007, except as described below.

Section 902.06 of the Manual sets forth the listing fees for certain securities with a term of less than seven years, including, but not limited to, warrants representing equity securities, index warrants, foreign currency warrants, contingent value rights and structured products. The Exchange proposes to revise Section 902.06 to exclude from its coverage those securities that will be subject to the fees set forth in new Section 902.09. The Exchange proposes to adopt new Section 902.09 to establish a new fee schedule for fees related to securities listed pursuant to Sections 703.15 (Foreign Currency Warrants and Currency Index Warrants), 703.17 (Stock Index Warrants Listing Standards) and 703.22 (Equity Index-Linked Securities, Commodity-Linked Securities and Currency-Linked Securities) of the Manual. The listing fees applicable to securities subject to Section 902.09 Manual are as follows:

Shares outstanding	Fee
Up to 1 million	$5,000
1+ to 2 million	10,000
2+ to 3 million	15,000
3+ to 4 million	20,000
4+ to 5 million	25,000
5+ to 6 million	30,000
6+ to 7 million	30,000
7+ to 8 million	30,000
8+ to 9 million	30,000
9+ to 10 million	32,500
10+ to 15 million	37,500
In excess of 15 million	45,000

These fees will apply each time an issuer lists a security of one of the classes specified in Section 902.09 of the Manual and also to subsequent listings of additional shares of the same security. The Exchange will treat each series of the security as a separate issue.

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

In addition, the following annual fees will apply to securities subject to Section 902.09: [3]

Shares outstanding	Fee
Up to 6 million	$10,000
6+ to 7 million	12,000
7+ to 8 million	14,000
8+ to 9 million	16,000
9+ to 10 million	18,000
10+ to 15 million	20,000
15+ to 25 million	25,000
25+ to 50 million	42,000
In excess of 50 million	55,000

These Annual Fees will be billed in January for the forthcoming year.

The proposed $2,500 fee for certain changes that involve modifications to Exchange records is applicable under the proposed fee schedule. This fee is consistent with the provisions of Sections 902.05 and 902.06 of the Manual.

The Exchange also proposes to amend Section 902.08 (Listing Fees for Debt Securities) of the Manual to reflect that the Automated Bond System is now ''NYSE Bonds.''

Finally, the Exchange currently applies the fee schedules set forth in Section 902.05 and 902.06 of the Manual to securities listed pursuant to Sections 703.15, 703.17 and 703.22 of the Manual. However, Sections 902.05 and 902.06 of the Manual do not identify Sections 703.15, 703.17 and 703.22 as securities to which the fees would apply. As a result, the Exchange requests permission to apply retroactively for the period from June 7, 2006 to October 2, 2007 the fee schedules set forth in Sections 902.05 and 902.06 of the Manual to all securities previously listed pursuant to Sections 703.15, 703.17 and 703.22 of the Manual. Beginning October 3, 2007, all securities listed pursuant to Sections 703.15, 703.17 and 703.22 of the Manual would be subject to the fee schedule set forth in Section 902.09 of the Manual.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act [4] in general, and Section 6(b)(4) of the Act [5] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its issuers and other persons using its facilities.

[3] The Exchange notes that it currently lists one Structured Product with 25 million shares or more outstanding.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(4).

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

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the NYSE consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2007–77 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2007–77. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2007–77 and should be submitted on or before November 16, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–21218 Filed 10–25–07; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56684; File No. SR–OCC–2007–12]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change Relating to Options on Leveraged ETF Shares

October 22, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on October 4, 2007, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which items have been prepared primarily by OCC. The Commission is publishing this notice and order to solicit comments on the proposed rule change from interested persons and to grant accelerated approval of the proposal.

[6] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would allow OCC to clear and settle options on exchange traded fund (''ETF'') shares generally known as ''Leveraged ETF Shares.''

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[2]

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to accommodate the introduction of options on ETF shares that represent interests in entities making a broad array of investments in order to provide investment returns that are equivalent to (a) a multiple of the percentage return of a specific stock index (''Multiple Fund Shares'' or ''Index Multiple ETFs'') or (b) a multiple of the inverse percentage return of a specific stock index (''Inverse Fund Shares'' or ''Index Inverse ETFs'') (Multiple Fund Shares, Index Multiple ETFs, Inverse Fund Shares, and Index Inverse ETFs are collectively ''Leveraged ETF Shares'').[3] According to the proposed rule changes filed by the exchanges seeking to list and trade Leveraged ETF Shares, the ETF issuing the Leveraged ETF Shares may make a variety of exchange-traded and over-the-counter investments, including stock index futures contracts, options on futures, options on securities, options on indexes, caps on stock, collars on stock, floors on stock, swap agreements, forward contracts, repurchase agreements, and reverse repurchase agreements.[4]

Currently, the definition of ''fund share'' in Article I, Section 1 of OCC's By-Laws lists the various underlying investments that may be made by the ETF issuing the fund share. In order to avoid creating an ever-lengthening list of possible investments that may prove to be non-exhaustive, OCC proposes to amend the definition of ''fund share'' to state that the term means ''a publicly traded security (as defined in Section 3(a)(10) of the Securities Exchange Act of 1934, as amended) that represents an interest in a trust, investment company, commodity pool, or similar entity holding and/or trading in one or more investments.'' [5]

The proposed rule change is consistent with the requirements of Section 17A of the Act because it (1) promotes the prompt and accurate clearance and settlement of transactions in options on Leveraged ETF Shares by applying the same basic rules and procedures to such options as are applied to options on other equity interests, (2) fosters cooperation and coordination with persons engaged in the clearance and settlement of securities transactions, (3) removes impediments to and perfects the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions, and (4) protects investors and the public interest. The proposed rule change is not inconsistent with the rules of OCC, including any rule proposed to be amended.

B. Self-Regulatory Organization's Statement on Burden on Competition

OCC does not believe that the proposed rule change would impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change, and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions.[6] By amending OCC's By-Laws so that OCC may clear and settle options on Leveraged ETF Shares that are to be listed and traded on Amex, the proposed rule change should help promote the prompt and accurate clearance and settlement of such securities transactions.

OCC has requested that the Commission approve the proposed rule prior to the thirtieth day after publication of the notice of the filing. The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the publication of notice because such approval will allow Amex to commence trading of options on Leveraged ETF Shares without any unnecessary delay.[7]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–OCC–2007–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2007–12. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the

[2] The Commission has modified parts of these statements.

[3] The ProShares Ultra Funds, which trades on the American Stock Exchange (''Amex''), is an example of a Multiple Fund Share or Index Multiple ETF. The Short Funds and the UltraShort Funds, which also trade on Amex, are examples of Inverse Fund Shares Index Inverse ETFs.

[4] File Nos. SR–Amex–2007–35 and SR–ISE–2007–87. The Commission recently issued an order granting approval of SR–Amex–2007–35 that allows Amex to list and trade options on Multiple Fund Shares and on Inverse Fund Shares. Securities Exchange Act Release No. 56650 (October 12, 2007), 72 FR 59123 (October 18, 2007).

[5] The Commission previously approved a supplement to the ''options disclosure document'' defining ''fund shares'' in a similar manner. Part III of the May 2007 Supplement to Characteristics and Risks of Standardized Options provides that the term ''fund shares'' includes interests in exchange-traded funds and other entities holding or trading in one or more types of investments. Securities Exchange Act Release No. 55702 (May 3, 2007), 72 FR 26671 (May 10, 2007) (File No. SR–ODD–2007–02).

[6] 15 U.S.C. 78q–1(b)(3)(F).

[7] *Supra* note 4.

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, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–OCC–2007–12 and should be submitted on or before November 16, 2007.

V. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular Section 17A of the Act and the rules and regulations thereunder.[8]

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–OCC–2007–12) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[9]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–21179 Filed 10–25–07; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2007–36]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATE: Comments on this petition must identify the petition docket number involved and must be received on or before November 15, 2007.

ADDRESSES: You may send comments identified by Docket Number FAA–2007–0007 using any of the following methods:

• *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.

• *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

• *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.

• *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, S.E., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tyneka Thomas (202) 267–7626 or Frances Shaver (202) 267–9681, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on October 22, 2007.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2007–0007.

Petitioner: Future Flight LLC.

Section of 14 CFR Affected: §§ 21.191(i)(1)(3) and 21.193(e)(1).

Description of Relief Sought: The petitioner is seeking relief to allow it to produce and sell experimental, ready-to-fly gyroplanes for operation in the light-sport category. The gyroplanes would meet all other provisions of §§ 21.190, 21.191 and 21.193, including the requirement that such aircraft meet the applicable consensus standard.

[FR Doc. E7–21105 Filed 10–25–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2007–38]

Petitions for Exemption; Summary of Petitions Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received.

SUMMARY: This notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before November 15, 2007.

ADDRESSES: You may send comments identified by Docket Number FAA–2007–29267 using any of the following methods:

• *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.

• *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

• *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.

• *Hand Delivery:* Bring comments to the Docket Management Facility in

[8] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[9] 17 CFR 200.30–3(a)(12).

Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• *Docket:* To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. Using the search function of our docket web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

FOR FURTHER INFORMATION CONTACT: Tyneka Thomas (202) 267–7626 or Frances Shaver (202) 267–9681, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on October 19, 2007.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

Petitions for Exemption

Docket No.: FAA–2007–29267.
Petitioner: AirNow.
Section of 14 CFR Affected: 14 CFR 61.45(a)(1)(i).
Description of Relief Sought: To allow AirNow to conduct type rating flight checks in either of two versions of the EMB–110 aircraft to satisfy the requirements under § 61.45.

[FR Doc. E7–21108 Filed 10–25–07; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2007–39]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before November 15, 2007.

ADDRESSES: You may send comments identified by Docket Number FAA–2007–28292 using any of the following methods:

• *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.

• *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

• *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.

• *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Madeleine Kolb, Transport Airplane Directorate, FAA at 425–227–1134.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on October 22, 2007.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2007–28292.
Petitioner: Embraer.
Section of 14 CFR Affected: § 25.1411(d)(2).
Description of relief sought: A grant of exemption would allow the storage of one life-raft in the Embraer ERJ 170–100 in a location other than that closest to the unplanned ditching exit.

[FR Doc. E7–21124 Filed 10–25–07; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Executive Committee of the Aviation Rulemaking Advisory Committee; Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the Executive Committee of the Aviation Rulemaking Advisory Committee.

DATES: The meeting will be on December 5, 2007, at 10 a.m.

ADDRESSES: The meeting will take place at the Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, 10th Floor, MacCracken Room.

FOR FURTHER INFORMATION CONTACT: Gerri Robinson, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–9678; fax (202) 267–5075; e-mail *Gerri.Robinson@faa.gov.*

SUPPLEMENTARY INFORMATION: Under section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), we are giving notice of a meeting of the Executive Committee of the Aviation Rulemaking Advisory Committee taking place on December 5, 2007, at the Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. The agenda includes:

• ISO Feedback.

• Report out from the Aviation Maintenance Technician Schools Curriculum and Operating Requirements Working Group to the Executive Committee.

• Issue Area Status Reports from Assistant Chairs.

- Future of ARAC.
- Continuous Improvement of FAA Rulemaking Process.
- Remarks from other EXCOM members.

Attendance is open to the interested public but limited to the space available. The FAA will arrange teleconference service for individuals wishing to join in by teleconference if we receive notice by November 26. Arrangements to participate by teleconference can be made by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Callers outside the Washington metropolitan area are responsible for paying long-distance charges.

The public must arrange by November 26 to present oral statements at the meeting. The public may present written statements to the executive committee by providing 25 copies to the Executive Director, or by bringing the copies to the meeting.

If you are in need of assistance or require a reasonable accommodation for this meeting, please contact the person listed under the heading **FOR FURTHER INFORMATION CONTACT**.

Issued in Washington, DC, October 16, 2007.

Pamela Hamilton-Powell,

Executive Director, Aviation Rulemaking Advisory Committee.

[FR Doc. E7–21107 Filed 10–25–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Ex Parte No. 661 (Sub-No. 1)]

Rail Fuel Surcharges

AGENCY: Surface Transportation Board, DOT.

ACTION: Notice of OMB Approval of Information Collection.

SUMMARY: Pursuant to the Paperwork Reduction Act, 44 U.S.C. 3501 *et. seq.* (PRA) and Office of Management and Budget (OMB) regulations at 5 CFR 1320.11, the Surface Transportation Board has obtained OMB approval for the collection of information adopted by the Board in *Rail Fuel Surcharges,* STB Ex Parte No. 661 (Sub-No. 1) (STB served Aug. 14, 2007).

This collection, which is codified at 49 CFR 1243.3, has been assigned OMB Control No. 2140–0014. Unless renewed, OMB approval expires on October 31, 2010. The display of a currently valid OMB control number for this collection is required by law. Under the PRA and 5 CFR 1320.8, an agency 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.

Vernon A. Williams,

Secretary.

[FR Doc. E7–21072 Filed 10–25–07; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Ex Parte No. 664]

Methodology to be Employed in Determining the Railroad Industry's Cost of Capital

AGENCY: Surface Transportation Board, DOT.

ACTION: Notice of public hearing.

SUMMARY: The Surface Transportation Board will hold a public hearing beginning at 10 a.m. on Tuesday, December 4, 2007, at its offices in Washington, DC. The purpose of the hearing will be to allow current parties of record to comment on the proposed methodology to be employed in determining the railroad industry's estimated cost of capital and the record developed in this proceeding. Parties of record wishing to speak at the hearing should notify the Board in writing.

DATES: The public hearing will take place on Tuesday, December 4, 2007. Any party of record wishing to speak at the hearing should file with the Board a written notice of intent to participate, and should identify the party, the proposed speaker, the time requested, and the topic(s) to be covered, as soon as possible but no later than November 20, 2007. Each speaker should also file with the Board his/her written testimony by November 27, 2007.

ADDRESSES: All notices of intent to participate and testimony may be submitted either via the Board's e-filing format or in the traditional paper format. Any person using e-filing should attach a document and otherwise comply with the Board's ''*www.stb.dot.gov*'' website, at the ''E-FILING'' link. Any person submitting a filing in the traditional paper format should send an original and 10 copies of the filing to: Surface Transportation Board, Attn: STB Ex Parte No. 664, 395 E Street, SW., Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: Timothy Strafford, (202) 245–0356. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at: (800) 877–8339.]

SUPPLEMENTARY INFORMATION: Each year the Surface Transportation Board (Board) determines the railroad industry's cost of capital. The Board then uses this cost of capital figure for a variety of regulatory purposes. It is used to evaluate the adequacy of individual railroads' revenues each year. It is also employed in maximum rate cases, feeder line applications, rail line abandonments, and trackage rights cases.

The Board calculates the cost of capital as the weighted average of the cost of debt and the cost of equity, with the weights determined by the capital structure (the fraction of capital from debt or equity on a market-value basis) of the railroad industry. While the cost of debt is observable and readily available, the cost of equity (the expected return that equity investors require) can only be estimated. How best to calculate the cost of equity is the subject of a vast amount of literature covering the fields of finance, economics, and regulation. In each case, however, because the cost of equity cannot be directly observed, estimating the cost of equity requires adopting a financial model and making a variety of simplifying assumptions. The Board currently uses a Discounted Cash Flow (DCF) methodology to calculate the cost of equity, which in turn is used to calculate the cost of capital.

By advance notice of proposed rulemaking served on September 20, 2006, the Board sought comments on the appropriate methodology to be employed in determining the cost of equity component of the cost of capital. On February 15, 2007, the Board held a hearing on the Board's cost-of-capital calculation, and how this evidence should be submitted and analyzed in future proceedings. On August 14, 2007, the Board proposed to move from a DCF method to a Capital Asset Pricing Model (CAPM) method in determining the estimated cost of capital. Generally, CAPM first determines the return an investor would receive on a risk-free investment. An estimate of the risk premium associated with the particular investment is then developed. Once the risk premium is quantified, its value is added to the risk-free investment rate to obtain an estimate of the cost of equity.

In the August 14, 2007 decision, the Board invited comments on the proposed methodology. A number of parties have commented on the importance of this proceeding and the Association of American Railroads

requested that the Board hold a hearing to discuss the proposed changes to the cost of capital calculation. This hearing should be a forum for parties to provide views and information about the Board's proposed changes and the record developed in this proceeding. The Board invites information and comments on the proposed CAPM methodology to calculate the rail industry's cost of capital.

Date of Hearing. The hearing will begin at 10 a.m. on Tuesday, December 4, 2007, in the hearing room at the Board's headquarters in Washington, DC, and will continue, with short breaks if necessary, until every person scheduled to speak has been heard.

Notice of Intent to Participate. Any party of record wishing to speak at the hearing should file with the Board a written notice of intent to participate, and should identify the party, the proposed speaker, the time requested, and topic(s) to be covered, as soon as possible, but no later than November 20, 2007.

Testimony. Each speaker should file with the Board a copy of his/her written testimony by November 27, 2007.

Board Releases and Live Audio Available Via the Internet. Decisions and notices of the Board, including this notice, are available on the Board's Web site at *http://www.stb.dot.gov.* This hearing will be available on the Board's Web site by live audio streaming. To access the hearing, click on the ''Live Audio'' link under ''Information Center'' at the left side of the home page beginning at 10 a.m. on Tuesday, December 4, 2007.

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Dated: October 24, 2007.

Vernon A. Williams,

Secretary.

[FR Doc. E7–21192 Filed 10–25–07; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 35079]

West Texas and Lubbock Railway Company—Acquisition and Operation Exemption—BNSF Railroad Company

West Texas and Lubbock Railway Company (WTLC),[1] a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to acquire, by purchase from BNSF Railway Company (BNSF), and operate approximately 37.5 miles of rail line known as the South Plains Subdivision, extending from milepost 330.1 west of Plainview, TX, to the end of the line at milepost 367.6 in Dimmitt, TX.

The transaction is expected to be consummated on or after November 10, 2007.

WTLC certifies that its projected annual revenues as a result of this transaction would not exceed $5 million and would not result in the creation of a Class II or Class I rail carrier.

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Stay petitions must be filed by November 2, 2007 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 35079, must be filed with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on John D. Heffner, John D. Heffner, PLLC, 1750 K Street, NW., Suite 350, Washington, DC 20006.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov*.

Decided: October 18, 2007.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E7–20926 Filed 10–25–07; 8:45 am]

BILLING CODE 4915–01–P

[1] Iowa Pacific Holdings, LLC owns WTLC through its wholly owned subsidiary Permian Basin Railways, Inc.

DEPARTMENT OF THE TREASURY

Office of the Secretary

List of Countries Requiring Cooperation With an International Boycott

In order to comply with the mandate of section 999(a)(3) of the Internal Revenue Code of 1986, the Department of the Treasury is publishing a current list of countries which require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

On the bais of the best information currently available to the Department of the Treasury, the following countries require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

Kuwait, Lebanon, Libya, Qatar, Saudi Arabia, Syria, United Arab Emirates, Yemen, Republic of.

Iraq is not included in this list, but its status with respect to future lists remains under review by the Department of the Treasury.

Dated: October 22, 2007.

John L. Harrington,

International Tax Counsel (Tax Policy).

[FR Doc. 07–5302 Filed 10–25–07; 8:45 am]

BILLING CODE 4810–25–M

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning an information collection titled, ''Examination Questionnaire.'' The OCC also gives notice that it has sent the information collection to OMB for review and approval.

DATES: Comments must be submitted by November 26, 2007.

ADDRESSES: Communications Division, Office of the Comptroller of the Currency, Public Information Room, Mailstop 1–5, Attention: 1557–0199, 250 E Street, SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874–4448, or by electronic mail to *regs.comments@occ.treas.gov*. You may personally inspect and photocopy comments at the OCC's Public Information Room, 250 E Street, SW., Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874–5043.

Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

Additionally, you should send a copy of your comments to OCC Desk Officer, 1557–0199, by mail to U.S. Office of Management and Budget, 725 17th Street, NW., #10235, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: You may request additional information or a copy of the collection from Mary Gottlieb, (202) 874–5090, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend the approval for the following information collection:

Title: Examination Questionnaire.

OMB Control No.: 1557–0199.

Affected Public: Businesses or other for-profit.

Type of Review: Regular review.

Abstract: The OCC has revised its Examination Questionnaire and updated the estimated burden hours to reflect the reduction in the number of national banks. Completed Examination Questionnaires provide the OCC with information needed to properly evaluate the effectiveness of the examination process and agency communications. The OCC will use the information to identify problems or trends that may impair the effectiveness of the examination process, to identify ways to improve its service to the banking industry, and to analyze staff and training needs. A questionnaire is provided to each national bank at the conclusion of their supervisory cycle (12 or 18-month period). A banker may now choose to complete this questionnaire on National BankNet, the OCC's extranet site.

Estimated Number of Respondents: 1,800.

Estimated Number of Responses: 1,602.

Frequency of Response: On occasion.

Estimated Time per Response: 0.17 hours.

Estimated Annual Burden: 267 hours.

Comments: A 60-day **Federal Register** Notice was issued on July 26, 2007 (72 FR 41105). No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has 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 on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: October 17, 2007.

Stuart Feldstein,

Assistant Director, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency.

[FR Doc. 07–5296 Filed 10–25–07; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Proposed Information Collection; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning its information collection titled, ''Assessment of Fees—12 CFR 8.''

DATES: You should submit written comments by December 26, 2007.

ADDRESSES: Communications Division, Office of the Comptroller of the Currency, Public Information Room, Mail Stop 1–5, Attention: 1557–0223, 250 E Street, SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874–4448, or by electronic mail to *regs.comments@occ.treas.gov*. You may personally inspect and photocopy comments at the OCC's Public Information Room, 250 E Street, SW., Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874–5043. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

Additionally, you should send a copy of your comments to OCC Desk Officer, 1557–0223, by mail to U.S. Office of Management and Budget, 725 17th Street, NW., #10235, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: You can request additional information or a copy of the collection from Mary Gottlieb, (202) 874–5090, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend OMB approval of the following information collection:

Title: Assessment of Fees—12 CFR 8.

OMB Control No.: 1557–0223.

Affected Public: Business or other for-profit.

Type of Review: Regular review.

Abstract: The OCC is requesting comment on its proposed extension, without change, of the information collection titled, ''Assessment of Fees—12 CFR 8.'' The National Bank Act authorizes the OCC to collect assessments, fees, and other charges as necessary or appropriate to carry out the responsibilities of the OCC. The OCC will require national banks to provide the OCC with ''receivables attributable'' data from independent credit card banks, that is, national banks that primarily engage in credit card operations and are not affiliated with a full service national bank. ''Receivables attributable'' are the total amount of outstanding balances due on credit card accounts owned by an independent credit card bank (the receivables attributable to those accounts) on the last day of an assessment period, minus receivables retained on the bank's balance sheet as of that day. The OCC will use the information to verify the accuracy of each bank's assessment computation and to adjust the assessment rate for independent credit card banks over time.

Estimated Number of Respondents: 11.

Estimated Number of Responses: 22.

Frequency of Response: Semiannually.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden: 22 hours.

Comments submitted in response to this notice will be summarized and 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 has 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 on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: October 17, 2007.

Stuart Feldstein,

Assistant Director, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency.

[FR Doc. E7–21069 Filed 10–25–07; 8:45 am]

BILLING CODE 4810–33–P

Federal Register

Friday,
October 26, 2007

Part II

Environmental Protection Agency

40 CFR Parts 9, 152, 156, 159 et al.
Pesticides; Data Requirements for Conventional Chemicals, Technical Amendments, and Data Requirements for Biochemical and Microbial Pesticides; Final Rules

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 158

[EPA–HQ–OPP–2004–0387; FRL–8106–5]

RIN 2070–AC12

Pesticides; Data Requirements for Conventional Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is updating its data requirements in part 158 of Title 40 in the Code of Federal Regulations for the registration of conventional pesticide products. As scientific understanding of potential hazards posed by pesticides has evolved, some data requirements have been imposed on a case-by-case basis but not codified since 1984. Besides providing the regulated community with clearer and more transparent information, the updated data requirements will enhance the development of health and environmental data to conduct scientifically sound chemical hazard/risk assessments to protect human health and the environment. In a companion final rule also being promulgated today, EPA is making technical changes arising from this final rule.

DATES: This final rule is effective on December 26, 2007.

ADDRESSES: EPA has established a docket for this action under Docket identification number EPA–HQ–OPP–2004–0387. All documents in the docket are listed on the regulations.gov web site. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Room S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202. This Docket is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: For information on the data requirements for ecological effects and environmental fate, contact: Ann Stavola, Field and External Affairs Division (FEAD), Office of Pesticide Programs (OPP) (7506P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (703) 305–5354; fax number: (703) 305–5884; e-mail address: *stavola.ann@epa.gov* . For all other questions, contact: Vera Au, FEAD (7506P), OPP, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:(703) 308–9069; fax number: (703) 305–5884; e-mail address: *au.vera@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 producer or registrant of a pesticide product, including agricultural, residential, and industrial, but not including antimicrobial pesticides, biochemical pesticides, or microbial pesticides.

This action may also affect any person or company who might petition the Agency for new tolerances, hold a pesticide registration with existing tolerances, or any person or company who is interested in obtaining or retaining a tolerance in the absence of a registration, that is, an import tolerance. This latter group may include pesticide manufacturers or formulators, importers of food, grower groups, or any person or company who seeks a tolerance. Potentially affected entities may include, but are not limited to:

Chemical Producers (NAICS 32532), e.g., pesticide manufacturers or formulators of pesticide products, importers or any person or company who seeks to register a pesticide or to obtain a tolerance for a pesticide.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) code has been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II.C. If you have any questions regarding the applicability of this action to a particular entity, consult the persons listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

A. What Action is the Agency Taking?

The Agency is updating and revising its data requirements for the registration of conventional pesticide products. The data requirements for the registration of antimicrobial products, product performance, and biochemical and microbial pesticides are not being revised in this action. EPA issued a proposed rule addressing data requirements for biochemical and microbial pesticides on March 8, 2006 (71 FR 12072). Antimicrobial data requirements have been moved to new part 161.

As scientific understanding of potential hazards posed by pesticides has evolved, some data requirements have been imposed on a case-by-case basis but not codified since 1984. By codifying the data requirements that have been applied on a case-by-case basis, the Agency believes the pesticide industry and other partners in the regulated community will be better prepared for the pesticide registration process.

B. What is the Agency's Authority for Taking this Action?

This rule is issued under the authority of FIFRA sections 3, 4, 5, 12, and 25; and FFDCA section 408.

C. Is this Final Rule Applicable to Antimicrobial Pesticides Products?

In current part 158, the data requirements cover both conventional and antimicrobial pesticides. Biochemical and microbial pesticides are set apart at § 158.690 and § 158.740. EPA proposed to limit the applicability of revised part 158 to conventional chemicals in anticipation of additional revisions tailored to biochemical, microbial, and antimicrobial pesticides. EPA received no key comments concerning the proposed limited applicability of part 158, and accordingly, EPA is adopting its proposed scope. Elsewhere in today's **Federal Register**, EPA is promulgating a final rule establishing data requirements for biochemical and microbial pesticides. However, EPA has not yet issued a proposed rule that would create separate data requirements tailored to antimicrobial pesticides.

If EPA were to maintain the proposed rule's exclusive application to conventional pesticides, the result would be that there would be no data requirements established by regulation for antimicrobial pesticides. Applicants would have to rely solely on consultations with EPA to determine the data requirements for their antimicrobial products without the benefit of regulatory data requirements. However, EPA has decided to preserve the current data requirements to provide regulatory coverage for antimicrobial

pesticides until the Agency can propose and promulgate a final regulation. To accomplish this, EPA has transferred intact the current data requirements of part 158 into a new part 161, entitled Data Requirements for Antimicrobial Pesticides. New part 161 will only apply to antimicrobial pesticides. Part 158 as promulgated today will only apply to conventional pesticides.

Part 161 is intended to be transitional and will be revoked upon the effective date of a replacement regulation tailored to antimicrobial pesticide data requirements. EPA recognizes that current data requirements of this transitional part are not optimal for registrants of antimicrobial pesticides. Because the 1984 data requirements were developed primarily to address agricultural chemicals, it has been difficult for antimicrobial registrants to discern data requirements that apply to antimicrobial products. This difficulty will not be corrected in simply transferring the current requirements to a new location. As a result, applicants should continue to routinely consult with the Agency to interpret the requirements of new part 161 as they apply to antimicrobial products. EPA supports and encourages the consultation process for all applicants, as the data requirements are highly dependent on pesticide type and use pattern. EPA is fully committed to the development of tailored data requirements for antimicrobial pesticides and expects to issue a proposed rule by the end of 2008.

III. Discussion of the March 11, 2005, Notice of Proposed Rulemaking (NPRM)

EPA published an NPRM on March 11, 2005 (70 FR 12275), proposing to update and revise its data requirements for the registration of conventional pesticide products in 40 CFR part 158. The data requirements identify the types of information that EPA needs to: determine that a pesticide product can be registered; issue a tolerance or tolerance exemption for pesticide residues in food; or allow the experimental use of the pesticide. The proposed rule was intended to: improve the scientific basis for pesticide decisions; update the requirements last codified in 1984; and reorganize part 158 to improve usability. These efforts will help protect human health and the environment by providing an up-to-date scientific framework for identifying and assessing the risks of conventional pesticides for use in the United States. The closing date of the 90–day comment period for the NPRM was June 9, 2005. The comment period was extended to September 7, 2005, to allow stakeholders additional time to assess the impact of the proposed revisions on their particular situations and prepare their comments (40 FR 33414). One hundred seven public comments were filed in Docket ID OPP–2004–0387. For a detailed response to comments, refer to Docket ID OPP–2004–0387. In addition, EPA convened a 2-day public workshop in Arlington, Virginia, to explain the provisions of the NPRM on May 3–4, 2005. There were 126 attendees at the public workshop.

IV. Discussion of Key Comments on the Order of Subparts

EPA's proposed rule structured the subparts of part 158 to match the original sequence of guidelines. A number of commenters found this structure confusing, and one commenter submitted an alternative structure, which was considered along with other alternative structures. EPA agrees with commenters that the current relatively random structure is not ideal for the average registrant who is seeking to determine the data requirements that apply to his product. Accordingly, in the final rule, EPA is restructuring the subparts to be more user-friendly.

EPA reasons that the users most in need of clarity are the infrequent, follow-on applicants, whose actual data requirements are in many cases limited to end-use product data of various types. In general, larger pesticide companies that routinely submit complex new chemical/new use applications and petitions for tolerance are responsible for the bulk of toxicology, residue chemistry, ecological effects and environmental fate data developed using the pure active ingredient (PAI), technical grade of active ingredient (TGAI) or the typical end-use product (TEP). In the case of exposure data, a variety of industry task forces, again primarily comprising large companies, are developing surrogate databases, so that newly generated data may not be necessary for many exposure scenarios.

In all these cases, FIFRA sec. 3(c)(1)(F) and its regulations in part 152 provide for the use of data developed by others, either under the formulators' exemption of section 3(c)(2)(D), or with appropriate permission or compensation offers. These provisions were put in place specifically to obviate the need for duplicate data development while protecting the rights of data submitters. Thus, smaller follow-on or me-too registrants often are required to generate only product-specific chemistry data, acute toxicity data, and efficacy data (generally designated in part 158 tables with End Use Product (EP) as the test substance). These applicants will benefit by the restructured part 158 so that they don't have to search for applicable data requirements by sifting through voluminous data requirements that may be satisfied by formulators' exemption, citation or offer-to-pay procedures.

EPA believes that major registrants will not be disrupted by a restructuring of the subparts because they are familiar with the data requirements, and, in any case, should be able to easily find the data requirement applicable to their product or petition in the current structure. Accordingly, EPA has restructured the subparts to place those data requirements applicable to the bulk of applications (new end-use products and me-too products) towards the beginning of part 158.

The resulting order does not correspond to the previous guidelines issued in 1982 *et seq*. (upon which the order of the proposed rule was based), or the sequence of the OPPTS Harmonized Guidelines. It is not critical that they do, as the tables refer to the appropriate individual Guideline for each data requirement.

The structure of part 158 in the final rule proceeds from product chemistry to efficacy to hazard/toxicity requirements of all types (human health, ecological toxicity) then exposure data requirements of all types (pre- and post-application human exposures, exposure to residues in food), and environmental fate, which overlap human exposure through drinking water, and ecological exposure, and spray drift. EPA has reserved subparts among these various segments for future additions on the same topic. EPA has also consolidated subparts addressing the same topics: plant protection data requirements (proposed as subpart J) have been incorporated into new subpart G (ecological effects data requirements) as have terrestrial and aquatic nontarget organisms data requirements (proposed as subpart E).

Finally, EPA intends that freestanding data requirements subparts such as biochemical pesticides, microbial pesticides, and antimicrobial pesticides be located at the end of the series. Product performance requirements, which span all categories of pesticides, would at present remain a separate subpart near the beginning of the series. In the proposed rule, EPA had reserved subpart P for Pesticide Management and Disposal but has removed the topic from the final rule while reserving subpart P. At present, EPA has no plans to develop data requirements specific to disposal. If EPA does so in the future, it will

determine where such requirements should be located.

EPA has placed data requirements for experimental use permits in subpart C of part 158. EPA eliminated the current use of brackets in each discipline to indicate which data requirements applied to an experimental use permit (see Unit VII.).

The final structure of part 158 is as follows:

Subpart A General provisions
Subpart B How to use the data tables
Subpart C Experimental use permits
Subpart D Product chemistry
Subpart E Product performance
Subpart F Toxicology
Subpart G Ecological effects [comprising aquatic, terrestrial and plant species]
Subparts H - I [Reserved]
Subpart J [Reserved] [Plant protection has been consolidated into subpart G]
Subpart K Human exposure [comprising pre-application and post-application exposure]
Subpart L Spray drift
Subpart M [Reserved]
Subpart N Environmental fate
Subpart O Residue chemistry
Subparts P - T [Reserved]
Subpart U Biochemical pesticides
Subpart V Microbial pesticides
Subpart W Antimicrobial pesticides
Subparts X - Z [Reserved]

V. Discussion of Key Comments on General Provisions of Part 158 (Subpart A)

A. Subpart A

EPA proposed revising subpart A by adding new material, deleting some portions, and revising the portions that were retained or relocated. The new material included definitions for ''applicant'' and ''registration,'' with references to definitions in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) that apply to part 158. Deletions from subpart A include: timing of the imposition of data requirements; flexibility of the data requirements; consultation with the Agency; agricultural versus non-agricultural pesticides; and biochemical and microbial pesticides.

EPA proposed deleting the section on minor uses but based on the comments and subsequent review, the Agency has in the final rule retained portions of the minor use section with an introductory paragraph. The section on the formulators' exemption was updated and relocated to 40 CFR part 152, subpart E.

B. Format for Data Submissions

EPA proposed minor revisions to § 158.32, describing how data are to be formatted for submission to EPA. Commenters supported revising Pesticide Registration (PR) Notice 86–5 to clarify provisions and avoid rejection of data for formatting reasons; one commenter also suggested integrating formatting guidance from PR 86–5 with § 158.32 in the final rule. The Agency has begun the process of updating the guidance in PR Notice 86–5 to further clarify the submission process. The improved guidance, together with consultation with the Agency, should help reduce the formatting conflicts. EPA will provide the public an opportunity to comment on the proposed revisions to PR 86–5. Since the details of the revisions are still underway, EPA has not changed the final rule.

C. Confidential Business Information

EPA proposed a number of minor revisions to § 158.33 concerning requirements for identification of and Agency treatment of confidential business information (CBI) under FIFRA sec. 10. These revisions were intended to clarify the provisions governing the Agency's ability to release information, and to bring the regulations in line with a court decision (District Court for the District of Columbia in *NCAP v. Browner, 941 F.Supp.* 197, 201 (D.D.C. 1996) supporting broader release of information to the public.

EPA received four comments concerning these proposed revisions, all from industry trade organizations. In general, the commenters disputed the Agency's positions or interpretations of the status of certain types of information as non-confidential (and therefore eligible for disclosure). One commenter misunderstood the provisions of FIFRA sec. 10 and based his comments upon an erroneous conception. EPA disagrees with all commenters and made no revisions in the final rule. EPA intends to abide by the Court decision which supports the Agency's interpretation of FIFRA sec. 10. EPA has responded to all comments in its Response to Comments document in the docket for this rule.

There were no comments on the confidentiality claims for plant-incorporated protectant information or on releasing information to state and foreign governments with consent.

D. Flagging Requirements

EPA proposed to revise the flagging requirements by updating and clarifying the criteria by:

- Reducing the number of study criteria from 11 to 7 by combining certain studies under one criterion;
- Combining reproductive, prenatal developmental toxicity and developmental neurotoxicity under one criterion to reflect the focus on infants and children.

Commenters requested clarification on the criteria and suggested the revisions would increase the burden to registrants. All of the listed flagging criteria need not apply to a toxicology study. If any of the criteria listed are applicable to the study, then the corresponding criterion number is to be included in the flagging statement submitted with the study. In the proposed rule, the Agency acknowledged that the revisions could flag more studies but this was expected because of the new types of toxicity studies to further protect infants and children. EPA made no revisions to the flagging requirements in the final rule. EPA has responded to comments in its Response to Comments document in the docket for this rule.

E. Data Waivers

EPA proposed reformatting the waiver process while retaining the provisions. Several commenters expressed their concerns about clarity, timelines and organization of information for waiver requests and made several suggestions. EPA refined data requirements and test notes to help the registrant determine if a waiver request is in order. Applicants are encouraged to discuss the waiver with the Agency before developing and submitting supporting data, information, or other materials. The Agency is committed to timely decisions and notification of the applicant. Organizational changes that were proposed will be retained for the final rule. EPA has responded to comments in its Response to Comments document in the docket for this rule.

F. Formulators' Exemption

EPA proposed to remove or revise provisions in part 158 that directly or indirectly arise from the statutory formulators' exemption of FIFRA sec. 3(c)(2)(D). First, EPA proposed to remove language in § 158.50 pertaining to the statutory formulators' exemption. Second, EPA proposed removing the asterisks denoting the application of the formulators' exemption to product chemistry and toxicology data requirements.

A number of commenters objected to the removal of formulators' exemption language, and others were confused by the removal of the asterisks. It is clear that commenters are confused by the distinction between the array of data that the Agency must have to determine whether a pesticide may be registered (the data requirements of part 158), and the means by which those data requirements are satisfied (the data citation and compensation provisions of part 152, subpart E, including the

formulators' exemption). In short, part 158 specifies the ''what'' and part 152 specifies the ''how'' of data requirements.

The primary purpose of part 158 is to specify the data requirements pertaining to a pesticide product. Part 158 was never intended to serve the broader purpose of specifying the various means by which an individual applicant can legally satisfy the data requirements: that is the purpose of the data compensation provisions of part 152. Part 152 explains all of the means of satisfying a data requirement specified in part 158, including submitting new data, citing existing data, citing to public literature, obtaining a waiver, or claiming eligibility for the formulators' exemption. EPA believes that it should reinforce this distinction by removing from part 158 what is actually incomplete information about the formulators' exemption.

Eligibility for the formulators' exemption is not a function of a data requirement. Rather, eligibility depends on the purchase of a registered product for incorporation into another product. The 1984 regulations erred in attempting to apply the formulators' exemption to specific product chemistry and acute toxicology requirements by means of the asterisk notation. First, the manner in which the asterisks were displayed was such that it was not clear precisely when the formulators' exemption did and did not excuse an applicant from the requirement to submit data. Further, it was unclear because it potentially conveyed the notion that the data requirement need not be satisfied. The fact that certain data need not be submitted or cited by an applicant eligible for the formulators' exemption does not mean that those data are not necessary to support the registration of the product, merely that the data requirement has been satisfied by another means. Usually the requirement has been satisfied by submission of data by the producer of the registered TGAI or manufacturing use product (MP) that the applicant purchases.

Additionally, maintaining information on the formulators' exemption in two locations in the Code of Federal Regulations is administratively cumbersome. As one commenter noted, the statute has been revised since both of these regulations were issued, and neither § 152.85 nor § 158.50 is accurate or complete. For this reason, EPA believes it is important to consolidate the formulators' exemption language in a single location.

All commenters correctly pointed out that although EPA indicated in the preamble that the formulators' exemption text of § 158.50 was to be relocated to part 152, no proposed regulatory language was included. EPA agrees that it did not include in the proposal the actual regulatory text that would be incorporated into part 152. In a companion final rule making technical changes, and which is published elsewhere in this issue of the **Federal Register**, EPA has included the revised language, which would incorporate the provisions of § 158.50 into § 152.85 with needed conforming text changes. EPA has also corrected § 152.85 to reflect current FIFRA sec. 3(c)(2)(D), as amended in 1988. Except where required as a result of these statutory amendments, EPA has made no substantive change to the exemption or EPA's interpretation of its applicability.

Although EPA believes that the formulators'exemption should properly be located in part 152 together with other provisions concerning submission or citation of data, the Agency recognizes the value of referring to the provisions of part 152 in part 158. Accordingly, EPA has revised § 158.70(a), by including a new paragraph (1) which explains that the provisions of part 158 should be read in conjunction with those of part 152, subpart E.

G. Minor Uses

EPA proposed to delete material in § 158.60 concerning minor uses. Minor use policies in existence in 1984 and information in anticipation of reregistration needs for data were included in original part 158. The information is by no means complete concerning EPA policies on minor uses, which have since expanded by statute. Nonetheless, several commenters wanted EPA to retain the information in paragraphs (a)(2) and (3). EPA has in the final rule retained paragraphs (a)(2) and (3), but has removed the remaining material and renumbered those paragraphs. The paragraphs being deleted have been superseded (the definition in paragraph (a)), are guidance only (paragraphs (a)(1) and (b)), or are covered by regulations elsewhere (paragraph (a)(4)).

H. Weight-of-Evidence Approach

The weight-of-evidence approach is referenced in part 158 under several disciplines. The approach requires a critical analysis of the entire body of available data for consistency and biological plausibility. Some considerations in this approach are listed below:

- *Sufficiency of data*. Studies that completely characterize both the effects and exposure of the agent have more credibility and support than studies that contain data gaps.
- *Quality of the data*. Potentially relevant studies are judged for quality and studies of high quality are given more weight than those of lower quality.
- *Evidence of causality*. The degree of correlation between the presence of an agent and some adverse effect is an important consideration.
- *Corroborative information*. Supplementary information relevant to the conclusions reached in the assessment is incorporated, e.g., studies demonstrating agreement between model predictions and observed effects. The weight-of-evidence considers the kinds of evidence available, how they fit together in drawing conclusions, and significant issues/strengths/limitations of the data and conclusions. Weight-of-evidence is not to be interpreted as simply tallying the number of positive or negative studies.

In the case of the developmental neurotoxicity (DNT) study, such a weight of the evidence approach is used when evaluating:

1. Treatment-related neurological effects in adult animal studies, such as:
- Clinical signs of neurotoxicity
- Neuropathology
- Functional or behavioral effects

2. Treatment-related neurological effects in developing animals, following pre- and/or postnatal exposure, such as:
- Nervous system malformations or neuropathy
- Brain weight changes in offspring
- Functional or behavioral changes in the offspring

3. Causative association between exposures and adverse neurological effects in human epidemiological studies

4. A mechanism that is associated with adverse effects on the development of the nervous system, such as:
- SAR relationship to known neurotoxicants
- Altered neuroreceptor or neurotransmitter responses

A compound could be subject to a DNT requirement under a variety of circumstances using these criteria in a weight of evidence approach that considers dose response, logical pattern of effects, data quality, biological plausibility, consistency of observations in the broader toxicological database, likeness of the case to structural analogues, and mode of action understanding. For example, the following scenarios for 3 different chemicals (chemicals A, B, and C) describe findings that could lead to the conclusion that a DNT study is needed. Chemical A is found to result in

responses consistent with an effect on the central nervous system (CNS): staggering (i.e., abnormal gait) at the mid and high doses and convulsions at the high dose are seen in a study, and abnormal gait at the mid and high doses and cortical lesions in the brain at the high dose are seen in another study. Chemical B is a GABA (gamma-aminobutyric acid) receptor antagonist (i.e., a CNS mode of action that block inhibitory systems that are involved in nerve responses) and is found to result in functional effects in the animal studies consistent with this mode of action, such as hyperactivity, altered response to sudden loud noises, and seizures (only at very high doses). In developmental toxicity studies, Chemical C results in dose-related microcephaly, a rare finding indicative of the brain neurons not proliferating normally.

However, a single effect would not necessarily always trigger a DNT. For example, a small decrease in brain weight at the highest dose tested in one adult animal study but no indications of neurotoxicity, including the lack of corresponding decreases in brain weight in other adequate toxicity studies, would not necessarily trigger a DNT. Similarly, a decreased response to stimuli at doses that result in significant body weight loss and poor health of the animal may not provide a weight-of-evidence basis for triggering the DNT.

VI. Discussion of Key Comments on the Data Tables (Subpart B)

A. Use Patterns

EPA proposed subdividing the current nine major use patterns to 15 major use patterns to fully address nonagricultural uses. Commenters asked for definitions of the proposed major use patterns and the phrases ''major use pattern,'' and ''pesticide use site groups.'' One commenter suggested adding a new major use pattern in addition to the ones proposed by EPA. Commenters also identified inconsistencies in major use patterns between the preamble and the regulatory text. EPA believed that the resulting use patterns from the subdivision of existing major use patterns were fairly self-explanatory and believed that adding the suggested terrestrial nonfood non-crop uses might create too fine a distinction and add to the already existing confusion. However, the Agency does appreciate the commenters' assistance in locating inconsistencies between the regulatory text and the preamble and believes the inconsistencies have been corrected.

One major use pattern in the proposed rule, Indoor medical, has been eliminated from the final rule. It is a use pattern primarily applied to antimicrobial products, not conventional pesticides, and will be considered for subpart W when proposed for comment. There were several variations of aquatic nonfood use patterns that commenters found confusing. The definition of the aquatic nonfood residential category was questioned by several commenters who assumed it referred to indoor tropical fish aquaria or koi fish ponds in yards. A survey of labels associated with this use category produced only a handful of products. Therefore EPA has consolidated the various aquatic nonfood use patterns into one aquatic nonfood use pattern, thus reducing the number of aquatic nonfood patterns to one. The elimination of Indoor medical and several aquatic nonfood use patterns reduced the final number of major use patterns. Thus, the final number of major use pattern for conventional pesticides will be 12, rather than the 15 in the proposed rule. The final 12 use patterns are: terrestrial food crop; terrestrial feed crop; terrestrial nonfood crop; aquatic food; aquatic nonfood; greenhouse food crop; greenhouse nonfood crop; forestry; residential outdoor; residential indoor; indoor food; and indoor nonfood.

In addition, not all the general use patterns will appear in the data table for each discipline. Some of the use patterns have been collapsed under a larger major use pattern for ease of use. For example, the major use patterns in the Toxicology Data Requirements table consist of Food and Nonfood. The discussion in § 158.500(b) explains that the general use patterns of terrestrial food crop, terrestrial feed crop, aquatic food, greenhouse food crop, and indoor food have been placed under the major use pattern Food. The Nonfood use patterns include products classified under terrestrial nonfood crop, aquatic nonfood, greenhouse nonfood crop, forestry, residential outdoor and indoor, and indoor nonfood. Therefore only two major use patterns appear in the data requirement table for Toxicology. Similar adjustments have been made to other disciplines as appropriate.

B. Appendix A

EPA proposed updating the current Appendix A, a compendium of pesticide use sites associated with major use patterns to assist registrants in determining which data requirements might apply to their products. EPA also proposed removing the updated Appendix A from 40 CFR part 158 and placing it on the OPP website and titled as *Pesticide Use Site Index*. This change in location would allow EPA to correct and update the pesticide use sites with some regularity without a complicated and lengthy rulemaking. Commenters either wanted to retain Appendix A in 40 CFR part 158 or were in favor of posting it on the OPP website. The latter were more concerned that the information be updated and revised more frequently. Since Appendix A is meant to be an index of pesticide use sites and major use patterns but not a requirement for applicants, EPA believes that it is more properly posted on the OPP website to assist applicants in locating the relevant pesticide use site(s) and the corresponding data requirements. Users are encouraged to submit comments and suggestions to the contacts listed on the Web page. OPP will update the Pesticide Use Site Index on a timely basis to keep the information current for users. Accordingly in the final rule, EPA has removed Appendix A from 40 CFR part 158. The information in the current Appendix A has been updated, titled *Pesticide Use Site Index*, and is available at *http://www.epa.gov/pesticides/regulating/registering/data_sources.htm*.

C. Test Substances

EPA is continuing its longstanding system of identifying test substances in the tables as follows: Technical grade of the active ingredient (TGAI); manufacturing-use product (MP); pure active ingredient (PAI); pure active ingredient, radiolabeled (PAIRA); end-use product (EP); and typical end-use product (TEP).

D. Required and Conditionally Required Data

Some commenters were confused by the explanations of R and CR in the proposed rule and requested tighter definitions and clarification of the test notes since the latter provided insufficient guidance. In the proposed rule, EPA requested comment on its R/CR designation, and received no suggestions for alternative means of presenting the data requirements. As described in the preamble to the proposed rule, the R/CR terminology is a general presentation of the likelihood that a data requirement will apply. The use of R does not necessarily indicate that a study is always required, but that it is more likely to be required than not. The use of CR means a study is less likely to be required. However, both R and CR designations must be read in the context of the accompanying test notes to provide context for the R/CR in the table. An applicant may assume that a data requirement with R will typically

be required all the time. The test notes accompanying that R designation may provide supplementary information or identify some condition(s) when the study is not required. A CR designation will generally include more extensive test notes describing the limited conditionality of the requirement. The final rule continues this longstanding practice. EPA revised some of the test notes to clarify the conditions under which the data would be required.

VII. Discussion of Key Comments on Identifying Data for Experimental Use Permits (EUPs) (Subpart C)

EPA requested comment on a way to identify data requirements for EUPs to replace the current bracketing system within each data table. A commenter suggested that EPA should separate out the data requirements applicable to experimental use permits, which have been expressed since 1984 by simply bracketing a registration data requirement in the tables. Other commenters misunderstood the bracketing, assuming that bracketed data requirements were somehow conditional in nature. EPA agrees that the bracket system diminishes the visibility of the EUP data requirements and leaves them scattered throughout the registration data requirements, and has therefore separated out and consolidated them. At the same time, EPA has updated the test notes to reflect those in the subparts on registration data requirements.

Because an experimental use permit is intended to precede a full registration, EPA has elected to place those data requirements early in the part 158 organizational structure. An alternative location for EUP data requirements would have been to locate them in part 172, thereby consolidating all EUP requirements in one place. However, examination of part 172 yielded no logical location for the data requirements except at the very end. Accordingly EPA has placed EUP requirements in subpart C of part 158, preferring to keep all data requirements pertaining to conventional pesticides in one place for ease of use. Where test notes for registration requirements have been revised based on comments to the proposed rule, in separating out EUP requirements, EPA has also revised those same test notes as they apply to EUPs.

VIII. Discussion of Key Comments on Product Chemistry Data Requirements (Subpart D)

EPA proposed a few changes in product chemistry requirements and it received a number of comments on elements of the data requirements that EPA had not proposed changing. They include:

- certified limits
- preliminary analysis
- submittal of samples
- definition of TGAI vs. MP
- statement of formula
- grouping of products to reduce or consolidate product chemistry requirements
- data on pesticide degradates

These comments are outside the scope of the proposal and may be considered for future revisions of part 158. Accordingly, EPA has not revised the final rule.

IX. Discussion of Product Performance Data Requirements (Subpart E)

EPA has transferred the contents of the product performance section (current § 158.640) essentially unchanged into the revised part 158. The regulatory text of the product performance section is reprinted in this final rule for clarity and completeness.

X. Discussion of Key Comments on Toxicology Data Requirements (Subpart F)

A. Data Requirements

1. *Immunotoxicity*. EPA proposed requiring functional immunotoxicity testing to evaluate the potential of a chemical to adversely affect the immune system since immune system suppression has been associated with increased incidences of infections and neoplasia. While the Agency understands that traditional subchronic and chronic rodent studies can provide much useful information on certain immunological endpoints such as hematology, lymphoid organ weights and histopathology, these studies do not provide a full and integrated evaluation of immune function. As a result of recommendations from the National Research Council (NRC) review and the FIFRA Scientific Advisory Panel (SAP), the Agency proposed requiring functional immunotoxicity testing along with the data from endpoints in other studies to assess the potential risk of pesticides on the immune system more fully.

Fifteen commenters submitted a variety of comments on this data requirement. All comments are addressed in the detailed Response to Comments document in the docket. Key comments are discussed in this unit.

Two commenters requested clarification of when this testing would be required and one commenter compared the U.S. requirement with that of the European Union (EU). Three commenters strongly supported including immunotoxicity testing in the toxicology data requirements for all pesticides. Six commenters opposed the codification of this data requirement on several bases and offered alternatives: divergence in immunological structure and response between species that gives animal studies limited predictive power for immunogenicity in humans; using data from other toxicity studies as a trigger for immunotoxicity studies; and changing from R to CR. EPA disagrees with these comments because data and analysis have shown that functional immunotoxicity testing, particularly when considered in conjunction with data already required by EPA on immunotoxic endpoints, is likely to increase EPA's ability to identify pesticides with immunotoxic effects. Additionally, functional immunotoxicity testing allows for better characterization of the possible effects of an immunotoxicant.

Three commenters had detailed technical questions about the test guideline which were not appropriate for discussion in part 158 since the latter concerns only data requirements. Their comments and suggestions were forwarded to the appropriate scientists for review and consideration in the context of guideline revision. While EPA agrees that the testing protocol may need further refinement, discussions on alternative testing paradigms will continue through the various scientific venues (e.g., International Life Sciences Institute/Health and Environmental Sciences Institute (ILSI/HESI) cooperative effort) as well as through future consultation with stakeholders on the development and validation of this test guideline.

EPA recognizes that there are a range of opinions on the necessity of an across-the-board requirement for functional immunotoxicity testing. However, EPA's judgment, as supported by the recommendations of the NRC and FIFRA SAP, is that there is value-added from requiring functional immunotoxicity testing for all pesticides. Therefore in the final rule, EPA retains a requirement for immunotoxicity testing on all food and nonfood pesticides on the TGAI. EPA has responded to comments in its Response to Comments document in the docket for this rule.

2. *Prenatal developmental toxicity*. EPA proposed amending the name of the requirement to correspond with the current terminology and to require two species for all nonfood pesticides. Commenters suggested making this requirement conditional based on results of other Tier 1 studies or on a

likely exposure pattern. EPA proposed requiring a second species because it believes the data will provide some assurance that the Agency will not be basing an assessment on a single species that might be highly sensitive (or the opposite) when compared to another. The final rule will maintain these changes to adequately characterize potential hazards to pregnant women and their fetuses.

3. *21–day dermal and 90–day dermal toxicity*. EPA proposed a 21– to 28–day dermal toxicity test for all food use pesticides since it is generally needed for worker risk assessments. Analyses of exposure information have shown that this duration of exposure is typical for agricultural workers in various components of their job. EPA proposed not requiring the 21– to 28–day dermal toxicity test for nonfood uses. However, if the dermal route is the primary route of exposure for nonfood uses, a 90–day study would be required because EPA believes the 21– to 28–day subchronic dermal toxicity test is insufficient to identify potential hazards.

Several commenters questioned requiring a 90–day study for nonfood uses when exposures rarely exceed 45 days. EPA considers the 21– to 28–day dermal study insufficient for nonfood use assessment because higher tiered oral studies (i.e., chronic or carcinogenicity studies) are not usually required for nonfood use pesticides. While 45–day exposures are common, EPA believes that they are not the maximum duration. For example, professional applicators may be subjected to repeated exposures during the 3 months of peak summer infestations. Since for many pesticides there is increased toxicity with increased exposure, professional applicators may not be adequately protected with 45–day studies. Existing regulations provide flexibility to implement alternative studies, on a case-by-case basis, as appropriate. Registrants should consult with the Agency if there is any question regarding the appropriate duration of the study. The highest level of hazard evaluation available for a nonfood use pesticide is satisfied through a subchronic toxicity test, i.e., a 90–day repeated exposure to the nonfood pesticide. Therefore, the final rule will require the 90–day dermal toxicity study for nonfood uses.

4. *Reproduction and fertility effects*. EPA proposed to require a reproduction study for nonfood uses but emphasized that the requirement is based on potential exposure. Commenters requested further clarification when the study would be required. Requiring the study for nonfood use pesticides would be based on a weight-of-evidence consideration of the toxicology data and potential exposure in terms of the frequency, magnitude, and/or duration. This is primarily an exposure-based data requirement and will not always be necessary. Registrants should consult with the Agency if there is any question whether the study must be conducted.

5. *Developmental neurotoxicity (DNT)*. EPA proposed that developmental neurotoxicity testing (DNT) be conditionally required for food and nonfood use pesticides. Thirteen commenters were unclear about the conditionality of this requirement and requested clarification about Test Note 27. Test Note 27 identified the effects to be considered in the weight-of-evidence approach.

One commenter questioned whether the results of standard tests in developing animals were sufficient to trigger a DNT test and whether the inhibition of cholinesterase activity (ChEI) would be the most sensitive effect for organophosphorus and N-methyl carbamate pesticides. The Agency has completed review of 20 DNT studies conducted with organophosphorus pesticides. In 13 out of 20 studies, ChEI was measured in the pups; cholinesterase was the most sensitive endpoint in those 13. Only a limited number of DNT studies are available for carbamates, and the endpoint for only one chemical was used to assess acute dietary risk.

Two commenters suggested amending the 2–generation reproduction study to include findings of thyroid effects, thus providing another criterion for DNT testing. Although such a criterion was included in the proposed weight-of-evidence approach, experience gained with the study resulted in the removal of this criterion. Instead, when thyroid effects of concern are observed, the Agency may require a more specific special study. In the final rule, EPA continues to encourage registrants to conduct DNT studies in combination with a 2–generation reproduction study when addressing the DNT requirement.

Ten commenters asked for clarification of Test Note 27 to indicate whether the listed effects were part of the approach and not individual triggers. EPA has revised this Test Note to eliminate the impression that the items in the list were individual triggers and referred commenters to its published Risk Assessment Guidelines for a more detailed explanation of the terms used in the test note. Due to an addition of a test note, Test Note 27 in the proposed rule was re-numbered to Test Note 28 in the final rule.

Therefore, the Agency is conditionally requiring the DNT study in the rat for food and nonfood pesticides. All available toxicology data for the pesticide will contribute to the weight-of-evidence determination of the need for a DNT study. The criteria for the weight-of-evidence determination are listed in Test Note 28 and include neurological effects from adult animal studies as well as neurobehavioral effects after pre- and post-natal exposure of the pesticide to young animals.

6. *Scheduled-controlled operant behavior, peripheral nerve function, and neurophysiology - sensory evoked potentials*. Commenters wondered if these tests would be commonly required and requested specific triggers for these studies. EPA discovered upon review that these studies were seldom required during the reregistration process and determined the studies could be removed from the table of commonly required studies. If the need arises in the future, the Agency may require any of these studies on a case-by-case basis. Validated OPPTS guidelines are in place.

7. *Non-rodent chronic studies (1–year dog study*). In the proposed rule, EPA considered eliminating the requirement because evidence from the published literature was consistent with EPA's belief from its reviews that the study may not be needed. EPA currently requires a 90–day dog study and a 1–year dog study for all food and nonfood uses to fulfill the non-rodent data requirements. EPA referenced published literature that suggested that the 1–year dog study may not be necessary. Based on a retrospective analysis of a large body of 1–year dog studies in its toxicology database, EPA proposed to eliminate the 1–year dog study but retain the 90–day study. EPA solicited review and comment by the FIFRA Scientific Advisory Panel (SAP) on the results of the preliminary analysis for reference dose (RfD) derivation on May 5–6, 2005 [Ref. 10].

The FIFRA SAP reviewed the Agency's retrospective analysis of the toxicity studies and encouraged the Agency to continue its analysis with a larger database. The FIFRA SAP made the following recommendations:

i. Increase the robustness of data analysis by including dog study datasets that were not used for the RfD determination.

ii. Conduct an analysis more representative of a prospective comparison through delineating the 13–week No Observed Adverse Effect Levels (NOAELs) and Lowest Observed Adverse Effect Levels (LOAELs)

independent of the 1–year study and establish data review criteria.

iii. Consider data analysis for separate classes of pesticides.

iv. Include additional background information on RfD that provides better perspectives for reviewing the Agency position paper.

v. Revise the title of the Agency position paper to reflect the purpose of the data analysis.

The FIFRA SAP said in its report that ''if the results of the analysis continue to indicate little added value from the 1–year dog studies, the Agency could move toward eliminating them on a stronger basis.''

In response, EPA conducted a more extensive analysis of dog toxicity studies on 110 chemicals representing over 50 different classes of pesticides [Ref. 12]. EPA concluded from this analysis that extending a dog toxicity study beyond a 13–week duration does not provide additional essential toxicity information; eliminating the 1–year dog toxicity study does not compromise the data needed for the determination of chronic RfDs and margins of exposure (MOE). Thus, reliance on the required chronic rodent studies, 2–generation rat reproductive study, and the 13–week dog toxicity study provides an adequate basis for chronic RfD derivation in pesticide risk assessment.

EPA acknowledges that there may be situations where a longer duration dog toxicity study may be warranted when a pesticide chemical is highly bioaccumulating (e.g. builds up in body fat) and is eliminated so slowly that it does not achieve steady state or sufficient tissue concentrations to elicit an effect during a 90–day study. EPA anticipates that this situation will be infrequent since current pesticides are not usually designed to be highly persistent and bioaccumulating. If such a chemical is encountered, EPA would require the appropriate Tier II metabolism and pharmacokinetic studies to more precisely evaluate bioavailability, half life, and steady state to determine if a longer duration dog toxicity study is needed. The circumstances that might lead to a request for the 1–year dog study are identified in Test Note 36.

B. Alternative Testing Paradigms

In the proposed rule published March 2005, EPA discussed the work underway on alternative testing paradigms by the International Life Sciences Institute (ILSI)/Health and Environmental Sciences Institute (HESI). EPA is in conceptual agreement with the ILSI/HESI philosophy of moving toxicology testing away from a rigid guideline-based screening approach and towards a more knowledge-based approach. The ILSI/HESI approach was published in a series of papers in the January 2006 issue of *Critical Reviews in Toxicology*.

Eleven commenters addressed the ILSI/HESI testing paradigm, all supporting its development and early adoption. One commenter suggested that EPA update the proposed rule with the ILSI/HESI study findings and reissue a revised proposed rule for comment. In a similar vein, another suggested incorporating a timetable into the final rule for modifying subpart F (Toxicology). Another commenter believed a number of the concepts developed in by ILSI/HESI were ripe for incorporation into pesticide testing requirements at this time. This same commenter suggested not finalizing the proposed rule until there was an opportunity to consider and incorporate the important concepts developed by Agricultural Chemical Safety Assessment (ACSA). EPA believes that incorporating the concepts into the final rule is premature since EPA has not had the opportunity to determine if the new testing paradigm will meet its risk assessment needs. EPA believes that delaying the remaining proposed changes which comprise the bulk of the proposal would be a disservice to the regulated community. In a differing view, a commenter was concerned about the lack of public interest representatives in ILSI-EPA discussions and recommended that EPA terminate its collaborative working relationship with ILSI and industry trade groups. Since the Agency is interested in more efficient risk assessment paradigms, it will continue to work with all stakeholders in investigating efforts in that direction and welcomes the participation of any public interest representatives in the discussions.

EPA is committed to moving towards a more efficient and refined testing/risk assessment paradigm. Given the Agency's experience with regulating pesticides over the last 30 years, the Agency is interested in improving certain aspects of the testing process. In particular, EPA is more attuned to risk assessment needs (i.e., an integrated approach) that avoids requesting data not used in risk assessment and that reduces and refines the use of laboratory animals.

In the proposed rule, EPA discussed the relevance and importance of the ILSI/HESI project, Agricultural Chemical Safety Assessment (ACSA): a Tiered Approach. This project, with the participation of EPA scientists, represents a pursuit of a more efficient and accurate tiered testing of pesticide chemicals. A series of reports authored by ILSI/HESI was published in a special edition of the *Journal of Critical Reviews in Toxicology* in January 2006, Volume 36, Issue 1 [Refs. 1, 2, 3 and 5], summarizing their findings and initial recommendations.

ACSA represents the first comprehensive effort to scientifically redesign the toxicology animal-testing framework for agricultural chemicals. The ACSA proposal is consistent with EPA's direction and goals to develop a more efficient and reliable testing paradigm. Under the ACSA scheme, some studies would be eliminated while endpoint coverage would be increased in redesigned studies based on responses observed in a core set of toxicity tests. The value of the scheme is that animals are more fully utilized and the need for some tests can be eliminated if the core set of tests or existing knowledge does not indicate a concern. Decisions on next steps must be made throughout the course of the study as a thorough evaluation of all available information, including data on the pharmacokinetics and mode of action of the pesticide (if such data exist), could lead to different conclusions regarding the appropriate way to approach testing.

For example, in the case of the developmental neurotoxicity study, for some chemicals, it might be concluded that adequate testing of the developing nervous system would be best accomplished with a standard developmental neurotoxicity study. Refinements to the guideline study could include, for example, changes to the route and/or duration of exposure (e.g., initiation of dosing to maternal animals prior to gestation day 6, or direct gavage administration to pups during lactation), the evaluation of appropriate biomarkers of exposure or effect, the use of more targeted functional, behavioral, or cognitive testing in offspring, or the histopathological and/or morphometric evaluation of particular regions of the central or peripheral nervous system that are known to be affected by either the chemical or chemical class. For other chemicals, the information in the toxicological database could lead to the conclusion that an alternative test should be performed instead of a guideline developmental neurotoxicity study. Alternative chemical-specific methods could be identified as a preferred option.

EPA has multiple activities underway to address the remaining science and policy issues associated with the ACSA proposal. One essential step towards

adopting the ACSA proposal will be conducting retrospective and prospective data analyses to determine whether this new testing paradigm will meet EPA's risk assessment needs as defined by statute. To this end, the Office of Pesticide Programs is currently working with EPA's National Center for Computational Toxicology (NCCT) to populate a Toxicological Reference Database (ToxRef). The current priority is to populate ToxRef with data from the rat 2-generation reproductive study, prenatal toxicity, and systemic toxicity studies on hundreds of pesticides that represent different classes, modes of action, and toxicity profiles. EPA will use this relational database to determine the value of endpoints currently evaluated in risk assessment (i.e., the F1 versus F2 responses). This analysis will provide scientific support for EPA's adoption of the proposal as the analysis will subject the ACSA proposal to a much broader set of chemicals than that used to develop the proposal.

Another critical step is gaining scientific consensus on the triggers (i.e., the points at which a concern is indicated and a higher level of testing is needed). The retrospective analyses will also be used to refine or confirm the ACSA proposed triggers for test decisions. Once the analysis is complete, EPA will be able to complete draft guidance on testing. The analyses and guidance are planned to be subject to SAP review and public comment in 2008.

Another essential step is testing how the ACSA scheme works in practice. There are plans to conduct several case studies using the ACSA tiered testing proposal. From these case studies, EPA will be able to assess the laboratory testing feasibility of such a complex study and to evaluate the ability of the approach and its parameters to characterize known toxicants and address risk assessment needs. Based on early scientific reviews, EPA scientists are already working on improvement of the ACSA tiered testing approach.

EPA will consider the results of the SAP review of the retrospective analyses and draft guidance, issues raised by stakeholders, and the case studies, in determining what revisions to current data requirements and testing guidelines may be appropriate. As the science issues are adequately vetted and crucial questions resolved, EPA will promulgate the appropriate regulatory changes on a timely basis. In the meantime, the existing regulations provide flexibility to implement any updated, new or novel testing schemes, on a case-by-case basis, as appropriate, until the changes are codified. Case-by-case determinations would be made in consultations with the Agency without the necessity of the waiver process.

It should be noted that ACSA is only one proposal that EPA will consider in improving the risk assessment process of environmental chemicals. Other relevant activities to consider include the National Academy of Sciences (NAS) recommendations on Toxicity Testing and Assessment of Environmental Agents expected in 2007 (Project ID BEST-U–03–08–A at *http://www8.nationalacademies.org/cp/projectview.aspx?key=74*), Organization for Economic Co-Operation and Development (OECD) Integrated Approaches to Testing and Assessment (*http://www.oecd.org/document/42/0,2340,en_2649_34377_36283562_1_1_1_1,000.html*), as well as predictive toxicity tools (QSAR, -omics, etc.) being developed by EPA's Office of Research and Development (ORD) Computational Toxicology Program (www.epa.gov/comptox). With regard to the OECD effort, EPA is currently playing a leadership role in planning a workshop scheduled for December 2007. The workshop will evaluate the current state of science and regulatory programs to evaluate pesticide inert ingredients and active ingredients using the data derived from *in silico* (performed on computer or via computer simulation), *in vitro*, and short-term *in vivo* models and bioassay systems.

Before considering regulatory changes to reflect the results of EPA's consideration of ACSA, NAS, and other recommendations, the Agency will develop scientific position papers on the new approach and recommendations for internal and external review. Internal review includes review by the FIFRA SAP and opportunities for public comment. External peer review as well as acceptability by other national and international regulatory authorities are crucial before implementation of any new testing paradigm and data requirements. Harmonization with the data requirements of these same authorities is also an important factor. International regulations currently require studies that were omitted in ACSA; this would pose significant problems for registrants if a harmonized approach is not adopted world-wide.

Lastly, EPA is committed to review part 158 data requirements frequently to incorporate new science that has been fully documented and peer reviewed.

XI. Discussion of Key Comments on Ecological Effects Data Requirements (Subpart G)

A. Generic Issues

EPA received comments in several areas that were common to all science disciplines under this subpart.

1. *Data harmonization and lack of availability of current guidelines*. The Agency received several comments stating that the data requirements for nontarget terrestrial and aquatic organisms, plants and environmental fate testing should not be promulgated if the test guidlines upon which the data requirements rely are not finalized. The Agency recognizes the importance of the connection between these data requirements and the guidance documents that provide information on how the data requirements may be satisfied. The Agency is in the process of updating its nontarget plant test guidelines with the OPPTS and the OECD. The terrestrial and aquatic animal guidelines are scheduled to be finished and available to the public by late 2007. Nonetheless, guidelines are guidance documents only, and the promulgation of data requirements does not depend on the availability of guidance documents.

2. *Elimination of species names in the test notes*. EPA eliminated the inclusion of preferred species names from the data requirements in subpart G. This does not represent an actual change in the requirements. Rather, the Agency determined that the indication of preferred species is a matter of guidance and should not be part of the requirements document. Species names are covered in the Agency's test guidelines, which are cited in the data requirements tables.

3. *Independent laboratory validation*. Concerns were raised by some commenters that the requirement to now have independent laboratory validation (ILV) of the chemistry methods used for residue measurements in the ecological and environmental fate field studies would add cost and time to these studies. They view these studies as already required and conducted under Good Laboratory Practice Standards (GLP) in 40 CFR part 160 for other data requirements. However, GLP Standards do not require an ILV. The requirement for an ILV has been in effect since the 1990s and, as such, is a codification of current practice. The ILV, as well as the original method validation, should be conducted under the GLP.

B. Data Requirements

1. *Terrestrial organisms.* i. *Acute oral toxicity test with a passerine species.* EPA proposed to require a second avian acute oral study on a passerine species (i.e., red-winged blackbird) to support all outdoor uses, including residential outdoor uses. The other avian acute oral study must be conducted on either a waterfowl or an upland gamebird, which has been standard policy. This revision of the avian acute toxicity data requirement elicited a significant number of comments. The comments not only concerned the addition of a passerine species to the avian acute oral data requirement, but also the test note which specifically named the red-winged blackbird (*Agelaius phoeniceus*) as the preferred passerine species. Some commenters suggested that the passerine requirement should be based on the results of either the mallard or bobwhite acute oral test results. They based their concerns on the fact that the red-winged blackbird is a wild species, and is not reared in a laboratory, unlike some commonly tested passerines as the canary and zebra finch. Because it is a wild species, the laboratories must request permits from the U.S. Fish and Wildlife Service (USFWS) to trap the birds. Also, there were concerns about the possible exposure of laboratory personnel to the avian flu virus from the trapped birds. Others suggested that EPA continue its policy of extrapolating the data from the mallard and bobwhite acute studies to passerine species in its risk assessments, and reserve the passerine study for cases when extrapolation does not significantly reduce uncertainty. Still others requested that the Agency consider other passerine species and provide a list of recommended species to the regulatory community, rather than prescribing solely the red-winged blackbird.

Based on these comments, in the final rule the Agency is no longer specifying the red-winged blackbird as the only acceptable passerine species for an additional avian acute oral toxicity study. However, the passerine acute oral study is still required, in addition to one with either the upland gamebird or the waterfowl. More than one tested species allows for consideration of interspecies sensitivity, and testing of a passerine addresses concerns that broad, untested avian taxa may be more sensitive than previously required mallards and bobwhites (Refs. 8 and 9).

EPA will consider studies using alternative species, as long as the alternative species meet the Agency's needs. EPA also intends to revise the avian acute oral toxicity guideline to include a passerine species, with the red-winged blackbird listed as among the preferred species. The Agency will revisit the issue of an acceptable species list with this goal in mind. Testing protocols may list other acceptable species upon reconsideration of this issue.

ii. *Japanese quail.* EPA did not propose to add the Japanese quail as a test species for the acute toxicity test and as an alternate for the avian reproduction test. Nonetheless, the Agency received two comments requesting that EPA accept the use of the Japanese quail as a test species, particularly as this species is accepted by OECD. The Agency presented its rationale for not listing Japanese quail as a preferred test species in its correspondence with OECD on March 24, 2003 (Ref. 14). Many years of domestication and artificial selection in this species may have biased the response of this species to chemicals. When comparing dietary study results of the same pesticide in both species the Japanese quail responds differently to toxicants, showing less sensitivity than the northern bobwhite quail. In addition, the EPA has a long history of requiring testing with the bobwhite and has accumulated a large database of acute toxicity results for this species. Abitrarily using another test species now would increase uncertainty and not add much value to the risk assessment process. Also the Japanese quail has an extremely high reproduction rate that is not representative of North American species, and therefore is not a suitable test species for the avian reproduction study.

iii. *Avian reproduction.* EPA proposed to change the requirement from conditionally required to required for terrestrial, aquatic, forestry and residential outdoor use patterns. Two commenters stated that the need for these data should be based on the pesticides' properties. EPA does not agree with the comments and has not revised the final rule. Adverse effects on avian reproduction can occur at levels of exposure several magnitudes lower than those that can cause acutely toxic effects. A pesticide's properties are not adequate predictors of avian reproduction effects.

One commenter advocated the development of reproduction tests with passerine species. Their interest was based on the fact that the current species used in this test, the mallard and the bobwhite, are precocial species (birds that are born covered with feathers, able to see and leave the nest soon after hatching) and passerine birds are altricial (birds that are born naked and blind and depend on their parents for food). The Agency believes that addressing the potential differences in reproduction between passerines and other birds is scientifically appropriate. However, at this time, no protocols have been made available to the Agency for such testing. Given the challenges testing labs are faced with for existing reproduction tests, protocols for passerines are not likely to be developed in the near future. Thus, the Agency is not expanding avian reproduction testing to passerine species at this time.

iv. *Wild mammal testing.* EPA did not propose to change the conditionality of the wild mammal toxicity test, but to maintain its requirement on a case-by-case basis. The Agency received three comments regarding this data requirement and its test note, which referred to some of the lower tier data that could indicate a need for the study. One comment stated that the test note was unclear, and asked for more specific guidance as to what avian or mammalian acute and subacute testing, fate characteristics and use patterns could trigger this data requirement. The second comment stated that wild mammal studies should only be triggered when the terrestrial risk assessment triggers a potential concern based on mammalian endpoints generated in the toxicology data package. A third comment proposed that the test note be revised to state that data on a wild mammal species may be required when the terrestrial risk assessment triggers a potential concern (acute RQ > 0.5; chronic RQ > 1.0) [RQ = Risk Quotient = exposure/toxicity] for a given use pattern based on laboratory toxicity endpoints and a refined exposure assessment.

The Agency evaluates the need for wild mammal toxicity on a case-by-case basis. The results of effects testing or fate testing alone are not the causal factor in such a determination. There may be case-specific information that would trigger the need for additional testing. This might include lines of information that suggest that available toxicity data provide unsuitable surrogacy for a particular nontarget species. Accordingly, the Agency has not revised the final rule.

v. *Acute toxicity studies with reptiles.* Although EPA did not propose acute toxicity studies with reptiles as test species, one commenter stated that effects on reptiles still are inadequately addressed in this new regulation. They do not believe that the avian studies adequately assess risks to reptiles.

The Agency will consider any peer-reviewed reptile testing protocols for

possible future addition in required testing. Information demonstrating a biologically significant difference in sensitivity or exposure between birds and reptiles, which would suggest that the bird risk assessment is not adequately protective, can still be considered in individual risk assessments.

vi. *Field testing.* The only changes that EPA proposed for the simulated or actual field testing for birds and mammals were to expand the requirement to include more use patterns under the conditional requirement, and to ask for independent laboratory validation of the chemistry methods. EPA did not propose to change the conditionality of the field test, but to maintain its requirement on a case-by-case basis.

EPA received five comments regarding the data requirement for simulated or actual field testing with terrestrial animals. One comment stated that the information provided in the test note for this data requirement was nebulous and asked for clarification. Three comments stated that additional testing, particularly with wild species in the natural environment, should only be conducted when refined risk assessments indicate a potential concern. The fifth comment supported the continued requirement of the study.

The Agency evaluates the need for field testing on a case-by-case basis. Field studies have traditionally been performed to address uncertainties in risk assessments, especially those risk assessments predicting environmental effects of concern. However, setting a conditional requirement that triggers such studies only when risk assessment tools predict adverse effects ignores the possibility that lines of information may conversely point out inadequacies of the existing tool to provide adequate protection. To this end, the Agency has retained the existing field testing data requirements in part 158.

One of the commenters proposed a change to the test note for the terrestrial field study (test note 6 in the final rule). Their rationale was that a refined risk assessment should be the basis for requiring this higher tier study. A refined assessment may indicate that field data are needed to resolve uncertainties in the risk assessment. If so, then the field test is required. The Agency agrees with the comment and changed test note 6.

vii. *TEP testing.* EPA proposed to expand the testing of birds in the acute oral and dietary studies to conditionally require testing with the TEP based on the results of these tests with the TGAI, environmental fate data and the use patterns.

A significant number of the comments the Agency received concerned the confusion in the data table regarding the use patterns that would need to be supported by TEP and the conditions that would trigger TEP testing with birds. Two commenters stated that TEP testing of birds should only be triggered when the risk from the TGAI is high, and birds are expected to encounter the intact end-use formulation in the field or expected to use the formulation itself as a food source. In contrast, a commenter recommended TEP testing for all products with potential aquatic or terrestrial nontarget exposure.

The Agency evaluates the need for testing of TEPs on a case-by-case basis. In such evaluations, the Agency relies on available lines of evidence such as published literature, adverse effects information submitted under FIFRA sec. 6(a)(2), European regulatory testing, and confidential statements of formula. The potential for nontarget organism exposure to TEP would naturally be a consideration as well. In light of the number of comments received on this issue, and past experience that shows TEP testing has only been required for granular formulations or other special situations, the conditional requirement has been removed from the data requirements and does not appear in the final rule. It will remain consistent with past policy and be required on a case-by-case basis.

2. *Aquatic organisms*—i. *Sediments.* EPA proposed to add testing of aquatic organisms exposed to treated sediment to better assess the effects of sediment-bound pesticides on aquatic environments. The whole sediment tests are acute toxicity studies of freshwater and marine invertebrates and a chronic study with invertebrates. The Agency received many comments about these newly codified data requirements. Most of the comments concerned the conditions for requiring these tests. The commenters cited not only the test notes, but also the sections of the draft preamble where the sediment data requirements were discussed in detail. Most asked for better guidance regarding the criteria for the studies. Several commenters also proposed alternative criteria for both studies. Some of the comments discussed risk assessment issues, or issues with the guidelines for the studies. These latter two areas are not the focus of this rule, and therefore, are not addressed in this document. The Response to Comments document has comprehensive details regarding these issues. Once the Agency determines or extrapolates that the use pattern has the likelihood for chemical exposure to an aquatic system the triggers for persistence and adsorption are reviewed. Toxicity will be taken into consideration relative to potential exposure. EPA will not define specific use patterns or applications that will not automatically require sediment testing.

Two criteria, the soil-binding ability and persistence of the pesticide, were the focus of many comments. The criteria, as listed in the proposal, are the soil partition coefficient (Kd) value ≥ 50 Liters/kilogram (L/kg) and the half-life of the pesticide in sediment ≤ 10 days for the acute test and > 10 days for the chronic test. Commenters asked for justification for the selection of the value of 50 for the Kd value.

The Agency's justification for selecting Kd ≥ 50 L/kg as a criterion for requiring the study was that this value would capture those chemicals with about 80% adsorption of a chemical to sediment organic carbon (2%). In the 1980s the Agency had proposed a Kd $\geq$ 3 to 10 L/kg as a trigger for adsorption. At that time the Agency put in place a Kd ≥ 50 L/kg. The Kd criterion represents the mean value observed in the soil adsorption studies.

EPA received a comment that questioned the appropriateness of using the Kd value as a trigger for sediment testing. They suggested that the trigger should be based on the results of the aquatic transformation studies, particularly the mass balance results and the half-lives in sediments. Their method indicated that pesticides with Kd values lower than 50 L/kg, our proposed value, could also bind to sediment.

Agency scientists re-analyzed the value for the Kd criterion with United States Geological Survey (USGS) data (Ref. 13) and found that Kd values for pesticides commonly detected in sediments can range as low as 1.6 and as high as 2,095. This analysis provided EPA with an important new perspective on Kd values, and the Agency considered lowering the value of the criterion. However, EPA decided not to change the Kd value from that in the proposed rule based on science and policy considerations. First, the Kd value, which indicates binding potential of the pesticide (unadjusted for dependency upon organic carbon) is not the primary factor in determining the need for sediment testing (i.e., persistence, toxicity and exposure are the main factors). More importantly, the Agency believes that such a change warrants input from the scientific community along with broader public input on the Kd trigger. The Agency

may consider changing the Kd value in future updates to part 158 requirements.

The criteria for persistence is determined by using the aerobic aquatic metabolism data and the aerobic soil metabolism data. The anaerobic soil metabolism data are not used for this purpose. Commenters questioned the half-life value of ≤ 10 days for the acute test and assumed it was a typographical error and should be ≥ 10 days. They also questioned if an acute study must be done prior to conducting the chronic study.

It appears from the above comments that the commenters misunderstand the purpose of the persistence trigger. Refer to Test Notes 21 and 22. EPA affirms that the intent of the triggers for the acute and chronic sediment tests are not to determine length of test. They were designed to determine if the sediment compartment should be considered for testing. Once that determination is made, then problem formulation will determine the specifics of the data required. The Agency strongly advises that the registrant consult with EPA concerning type of study and test organism selection. The Kd trigger is the same for either the acute or chronic sediment test. It is the persistence (i.e. half-life) that drives the decision regarding which study to require. For example, if the soil or aquatic aerobic/anaerobic half-lives are less than 10 days (Agency policy is to use the most conservative value, unless evidence is provided to support the use of an alternative value), then the Agency would accept the 10 day (acute) sediment study, unless there are clear reproductive issues *a priori*. For half lives greater than 10 days, a 28 to 65 day (chronic) study would be more appropriate. Consultation with the Agency is needed if the registrant is uncertain as to which length of study is appropriate.

Two commenters proposed that a value of log Kow > 3 is a more commonly used value with which to judge whether a compound might have adsorptive potential. EPA agrees that the Kow, along with the Koc, are valid environmental fate values to use as criteria for these studies. The log Kow of 3 is equivalent to a Koc value of 1,000. Both values are frequently more available than either the Kd or half-life values. Consequently, the requirement for submission of sediment studies can be determined by either of these two values. The test notes in the final rule have been revised to include the Kow and Koc.

One commenter wanted EPA to specify in the test notes when freshwater or marine organisms must be tested for sediment toxicity. Sediment toxicity data are required for marine/estuarine test species if the product is intended for direct application to the estuarine or marine environments, or the product is expected to enter this environment in significant concentrations, either by runoff or erosion, because of its expected use or mobility pattern. The test notes are amended to clarify when marine organism testing is required.

ii. *Fish acute toxicity testing*. EPA proposed that indoor and greenhouse uses would only require one fish acute toxicity test, unless the chemical is stable in the environment, in which case, a second fish test with a different species is required. The Agency received three comments regarding the fish acute data requirement. The comments asked for clarification regarding the number of freshwater fish studies that are now required to support greenhouse and indoor uses.

With regard to greenhouse and indoor uses, the Agency requires the testing of one fish species to adequately assess the hazards to fish. If the LC_{50} is < 1 ppm, no other fish species testing is required. However, if the LC_{50} is between 1 - 10 ppm, a second species will be required to substantiate the potential for hazard to aquatic organisms.

iii. *Fish and invertebrate chronic toxicity testing*. EPA proposed several revisions to clarify the applicability of the requirements for the chronic toxicity tests. The Agency received one comment requesting more information on the fish early life stage test and the invertebrate life cycle with saltwater organisms. Another comment suggested that the Agency take into consideration the difficulties of using estimated environmental concentration-based triggers for the chronic studies.

The Agency affirms that chronic studies are required to support registration of an end-use pesticide product that is applied directly to water or is expected to be transported to water from the intended use site. This condition applies to estuarine as well as freshwater environments. These study requirements reflect the uncertainty that surrounds pesticide exposure and their potential for impact to aquatic organisms. Since exposure is a major driving parameter in assessing acute and/or chronic risk, this factor must be defined and addressed. The test notes for these studies list the details.

iv. *Testing with estuarine organisms*. EPA proposed to change the conditionality of the acute testing from conditionally required to required for several use patterns. The comments regarding this set of data requirements primarily addressed test species and TEP testing with estuarine organisms.

The commenters stated that proposed test notes 13 and 15 were inconsistent with regard to the preferred estuarine fish species in the test note. As discussed in the Generic Issues unit (Unit XI.A.), the test notes in the final rule no longer indicate the names of preferred test species as they are fully discussed in the appropriate guidelines.

The comment regarding TEP with estuarine organisms is similar to that for TEP testing with freshwater organisms discussed in Unit XI.B.2.vii., except that the commenter recommended estuarine organisms should only be tested with the TEP if testing with the TGAI indicated that estuarine organisms are more sensitive than freshwater organisms, or if the freshwater organism tests demonstrate that the TEP is more toxic than the TGAI. The Agency response to the comment on TEP testing is addressed in Unit XI.B.2.vii.

v. *Testing of degradates*. EPA did not specifically propose any data requirements requiring toxicity testing with degradates of pesticides. However, one commenter stated that degradates should be included as they can also present significant environmental risks. The Agency requires appropriate testing of a pesticide's degradates on a case-by-case basis. If the environmental fate data show the degradates can potentially persist, and subpart F toxicology data show they are toxic, then aquatic toxicity testing is required.

vi. *Bioaccumulation testing*. EPA proposed to eliminate the requirement for these studies for aquatic nonfood residential or residential outdoor uses since the exposure is expected to be minimal. One comment asked for clarification as to when they would, most likely, be required. The Agency anticipates that these studies may be required on a case-by-case basis depending on the results of lower tier ecological toxicity tests and potential environmental fate characteristics. The potential for accumulation is triggered when a chemical has a half-life ≥ 4 days and log Kow ≥ 3.

EPA proposed to change the conditions under which the accumulation in fish and accumulation in aquatic organisms would be required. EPA received eight comments regarding the fish and nontarget organism accumulation studies. Three of the commenters suggested that this data requirement be placed in proposed subpart E (now subpart G), Terrestrial and Aquatic Nontarget Organism Data Requirements, and not proposed subpart N. There were two comments stating that test note 10 was well written, and

should also apply to the aquatic nontarget organism accumulation study requirement in lieu of test note 11 in the environmental fate data table. They suggested that this test note is also appropriate for the three accumulation studies in proposed subpart E, bioavailability, biomagnification and toxicity of aquatic organisms.

The Agency agrees with the comments, and has moved the two studies under proposed subpart N, Accumulation in Fish and Accumulation in Aquatic Nontarget Organisms to subpart G, under the data requirements for aquatic organisms - bioavailability, biomagnification and toxicity. Therefore, all the ecological and fate requirements related to bioaccumulation are located solely in subpart G. We also agree with the comment that the language of Test Note 10 (Accumulation in Fish) in the proposed environmental fate data table is appropriate for the Accumulation in aquatic nontarget organisms data requirement in subpart G. Test note 10, ''Not required when the octanol/water partition coefficients of the pesticide and its major degradates are less than 1,000; or there are no potential exposures to fish and other nontarget aquatic organisms; or the hydrolytic half-life is less than 5 days at pH 5, 7, and 9.'' was moved to subpart G and renumbered as test note 19. This test note replaces test note 21 in proposed subpart E (now subpart G).

vii. *Testing with TEPs*. EPA proposed to require acute testing with the TEP for freshwater and estuarine organisms based on the introduction of the TEP directly into an aquatic environment, or the estimated environmental concentration of pesticide equaled or exceeded one-half the LC_{50} of the TGAI when the end-product was used as directed, or an ingredient in the formulation was expected to enhance the toxicity of the active ingredient or to directly cause toxicity to aquatic organisms. One comment recommended that TEP testing with estuarine organisms should be conditional based on the results of TEP testing with freshwater organisms, or if estuarine organisms were more sensitive to the TGAI than were freshwater organisms.

The Agency requires TEP testing of freshwater and estuarine organisms for all outdoor uses. As the environments of the estuarine and freshwater organisms are different, how the chemical ingredients that comprise a formulated product will react in the different aquatic systems cannot be readily predicted. Therefore, the responses of each group of organisms are independent of each other, necessitating testing of both freshwater and estuarine organisms with the TEP in addition to the TGAI, if the triggers in the test note 9 are met.

3. *Nontarget plant testing*. EPA proposed to eliminate the requirement for the seed germination study because the information from this study can also be obtained from the seedling emergence study. The germination study has not been required for several years, so its removal from the final rule simply codifies the current standard practice. Commenters agreed with this change.

EPA proposed to expand Tier I and Tier II seedling emergence, vegetative vigor and aquatic plant growth studies to include terrestrial food and feed crops, aquatic food crops, forestry and residential outdoor uses. The conditional requirements for Tier III phytotoxicity terrestrial and aquatic field studies were also expanded with the addition of the same use patterns. The use patterns were expanded beyond terrestrial and aquatic nonfood uses and forestry uses in order to capture scenarios which may be impacted by drift and runoff from pesticide applications in neighboring areas.

Two comments requested explanations for including outdoor residential uses and indoor uses among those requiring plant testing. Outdoor residential use patterns are now included among the sites requiring plant testing because data indicate that herbicide uses on sites such as turf can harm nontarget plants through runoff. Turf is classified as an outdoor residential terrestrial use, and therefore requires nontarget plant testing. The Agency acknowledges that including indoor uses among those requiring aquatic plant growth testing in Table 3 in the proposed rule was an error as EPA did not intend to propose such a requirement. Plant testing is not required for indoor uses. Additionally, testing for aquatic nonfood residential use, also included by error in Table 3, has been eliminated in the final rule.

i. *Test substance*. EPA proposed to change the test substance for the terrestrial plant studies from TGAI to TEP. This change was made to address Agency concerns that end-use products can contain ingredients that enhance the bioavailability or toxicity of the active ingredient. Seven commenters expressed concerns regarding the change in the test material to the TEP for the terrestrial plant studies. They preferred to continue to use the TGAI as the test substance. The most common concern expressed by the commenters was the possibility that the final composition of the end-use product under development may differ from the product used in testing. EPA recognizes this may occur, but the TEP is required as the test material because the formulations contain adjuvants and other chemicals that aid the movement of the active ingredient into the plant, making it more effective, and therefore, possibly more toxic to nontarget plant species. The Agency has been routinely requesting nontarget terrestrial plant tests with TEP for a number of years, so this change is codifying current policy and reflects the needs of the Agency in assessing impacts on nontarget organisms.

ii. *Species testing*. Recommended plant test species are not designated in part 158, but are included in the guidelines for conducting the studies. Species issues should be addressed in the context of guideline development and revision and not the data requirements. Accordingly, EPA has not revised part 158 based on comments about the plant test species.

iii. *TIER III guidelines*. The only changes that EPA proposed for the Tier III terrestrial and aquatic field studies for nontarget plants was to expand the requirements to include more use patterns under the conditional requirement, and to propose independent laboratory validation of the chemistry methods. EPA did not propose to change the conditionality of the field test, but to maintain its requirement on a case-by-case basis. The Agency received three comments regarding the field testing study guidelines and the process of problem formulation and refinement of the ecological risk assessments. They recommended that the field studies be conducted within the context of problem formulation to characterize risks to plants under actual use conditions. These comments relate more towards guidance about the field studies and not to the data requirements themselves. As such, these comments are being considered in context of revisions to guidelines and not to this final rule.

iv. *Test note revisions*. The vegetative vigor studies are no longer required for granular and bait formulations. This change acknowledges that these formulations are not practical test materials, as the vegetative vigor study requires the test substance to be applied directly to the plant surface.

The Agency received one comment regarding an apparent error in the placement of test note 3 for the Tier I and Tier II seedling emergence studies. EPA acknowledges that test note 3 was inaccurately placed next to the seedling emergence studies. This has been

corrected, and this test note now refers to the Tier I and Tier II vegetative vigor studies.

v. *Test notes 5 and 6—the conditions for moving from Tier I to Tier II studies.* EPA received one comment asking for clarification of test notes 5 and 6 of the proposed rule. The Agency agrees that the wording of both test notes is ambiguous, and rewrote both test notes. Test notes 5 and 6 in § 158.660 are now accurate. The draft test notes implied that all the plants tested in the tier I studies were also required to be tested in Tier II. We rewrote the two test notes to clarify that only the plant species that exhibited the stated level of the detrimental effect are required to be tested at Tier II.

Another commenter referred to the findings of the FIFRA SAP in 2001 when it convened to discuss the proposed NAFTA (North America Fair Trade Act) Nontarget Plant Toxicity Tests. [Ref. 4] The FIFRA SAP indicated that progression from Tier I to Tier II should be based on a statistically significant effect > 10% relative to the control for aquatic plants and between 50% to 25% for terrestrial plants. This commenter recommended that, as a conservative approach, EPA should use the 25% for progression from Tier I to Tier II for terrestrial plant studies. For terrestrial plants, the Agency agrees that the progression from Tier I to Tier II testing will remain 25% inhibition or greater. However, effects seen at less than 25% may raise concerns for federally listed threatened and endangered species, and additional testing at Tier II may be needed to mitigate the presumption of risk to listed species.

4. *Insect pollinator testing.* EPA eliminated the requirement for a honey bee subacute feeding study as the information from this test can be covered under the field study requirement. The proposed rule listed four requirements for testing of aquatic insects and terrestrial predators and parasites. Even though EPA did not propose to delete these requirements, continuing to include potential data requirements that have not been routinely imposed and for which no guidelines have been developed, serves no useful purpose. Therefore EPA eliminated these four data requirements in the final rule.

The Agency also proposed to include additional use patterns and exposure scenarios under the data requirement for the honey bee acute contact toxicity study. Previously, the requirement was limited to outdoor use patterns when the crop may be in bloom and thereby attractive to honey bees. The change addresses not only blooming but also pollen-shedding and nectar-producing parts of nontarget plants that may be attractive to honey bees and may be in or near the site of a pesticide application. The criteria for requiring the honey bee residue study was corrected from an LD_{50} value of < 1 microgram/bee for the acute contact study to < 11 micrograms/bee, as originally published in 1982 (48 FR 53192).

There were several comments pertaining to the field study requirement for pollinators concerning the criteria that the requirement could be based on data from arthropods other than bees. These commenters asked for clarification to confirm that the data pertain solely to terrestrial and not aquatic arthropods. The test note for the pollinator field study was modified to clarify this point. Another comment concerned the designation of the acute contact toxicity study as R for the aquatic uses, citing several application scenarios or formulation types, such as direct application to water or granular formulations, that would reduce exposure to honey bees. The Agency agrees with the comment and changed the requirement for aquatic uses to CR.

XII. Discussion of Key Comments on Human Exposure Data Requirements (Subpart K)

A. Applicator Exposure

A commenter recommended that EPA rely on surrogate data from other agencies such as the Occupational Safety and Health Administration's (OSHA) permissible exposure limits that are regulatory limits on the amount of concentration of hazardous substances in the air. Other commenters indicated that exposure data were available from several reliable sources besides the Pesticide Handlers Exposure Database and the Outdoor Residential Exposure Task Force mentioned in the proposed rule. These commenters identified other task forces that have generated exposure data—Indoor Residential Exposure Task Force, the Agricultural Handlers Exposure Task Force, and the Agricultural Reentry Task Force.

The Agency assumes that the commenter is referring to Permissible Exposure Limits (PELs) when he speaks of ''OSHA workplace exposure limits.'' The Agency does consider regulatory levels set by other authorities during risk assessment, including OSHA PELs; however, EPA and OSHA have different legislative mandates. OSHA does not have the authority under FIFRA to regulate pesticide exposures and therefore does not set PELs for chemicals used solely for pesticides.

The Agency has a long history of relying on surrogate exposure data and databases. To estimate occupational and residential exposures, the Agency uses databases containing large numbers of measured values of dermal and inhalation exposure for pesticide workers. Using these measured data from one study/scenario as surrogate or generic data for another study/scenario is appropriate since it is generally believed for pesticides of low volatility that the physical parameters of the handling and application process (e.g. the type of formulations, the method of application, and the type of clothing), not the chemical properties of the pesticide, control the amount of dermal and inhalation exposure. In contrast, OSHA evaluates exposures on a site-specific basis by collecting samples on workers and does not rely on surrogate databases.

However, for certain types of pesticide formulations or use scenarios, there is no exposure data, and therefore, it is not possible to perform an occupational/residential risk assessment. This is particularly one of the types of situations in which the Agency would require chemical-specific exposure data.

Some commenters questioned the currency of several guidelines in the context of dermal exposure and inhalation exposure data requirements. EPA will consider the comments as its scientists work to revise/update the guidelines. The Agency has reviewed and accepted many studies that are not conducted in accordance with current guidelines, but which serve its needs and provide suitable information for risk assessment purposes. In addition, some guidelines have not been finalized but are available in draft form. Notwithstanding such flexibility, EPA intends to finalize these test draft guidelines by the end of 2008.

EPA made no revisions in the final rule. EPA received other comments on this topic and has responded in its Response to Comments document in the docket for this rule.

B. Post-Application Exposure

EPA proposed changing several existing post-application data requirements from CR to R, expanding the use sites that those data requirements cover to include residential uses sites, and codifying certain data that had been previously sought on a case-by-case basis. Currently, EPA frequently conducts post-application exposure assessments, particularly with regard to residential

exposures, based upon conservative extrapolations from generic data. The new data will ensure that EPA can more realistically assess post-application exposure. The possibility of using generic task force data or modeling for dermal and inhalation exposure was suggested by many commenters because some of the studies might place additional testing burdens on formulators as to products that did not raise safety concerns under very conservative modeling. EPA believes that modeling and generic task force data would be acceptable absent any specific problems. Registrants who are not members of task forces need to submit their own data or otherwise satisfy the data requirements. Comments about surrogate exposure data and the Task Forces that generate them arose in the following data requirements: Product use information; description of human activity; nondietary ingestion exposure; and dislodgeable foliar residue dissipation and turf transferable residues.

Commenters also identified test guidelines that still exist only in draft form and are absent from the list of OPPTS harmonized guidelines. EPA agrees that these test guidelines need to be finalized and intends to finalize them by the end of 2008.

EPA made no revisions in the final rule. EPA received other comments on this topic and has responded to comments in its Response to Comments document in the docket for this rule.

XIII. Discussion on Spray Drift Data Requirements (Subpart L)

EPA has transferred the contents of the spray drift section (current § 158.440) essentially unchanged into subpart L of part 158. The regulatory text of the spray drift sections is reprinted in this final rule for clarity and completeness.

XIV. Discussion of Key Comments on Environmental Fate Data Requirements (Subpart N)

A. Generic Issues

1. *Data harmonization and lack of availability of current guidelines.* The Agency received several comments stating that the data requirements for nontarget terrestrial and aquatic organisms, plants and environmental fate testing should not be promulgated if the test guidelines upon which the data requirements rely are not finalized. The Agency recognizes the importance of the connection between these data requirements and the guidance documents that provide information on how the data requirements may be satisfied. Guidelines are scheduled to be finished and available to the public by late 2007. Nonetheless, Guidelines are guidance documents only, and the promulgation of data requirements does not depend on the availability of guidance documents for each group of guidelines.

2. *Independent laboratory validation (ILV).* Concerns were raised by some commenters that the requirement to now have ILV of the chemistry methods used for residue measurements in the ecological and environmental fate field studies would add cost and time to these studies. They view these studies as already required and conducted under GLP 40 CFR part 160 for other data requirements. The requirement for an ILV has been in effect since the 1990s. The ILV, as well as the original method validation, is subject to the GLP.

3. *Data requirements*—i. *Hydrolysis.* The Agency received three comments on the hydrolysis data requirement. Two comments questioned the addition of indoor uses to the use patterns that require this study. EPA included several sites that are considered indoor, but where environmental exposure may be likely. These sites include agricultural premises, in or around farm buildings, barnyards, beehives, and fish or seafood processing premises. The expansion of the use patterns requiring this study reflects concern about the potential movement of pesticides and their degradates into the environment.

ii. *Photodegradation, laboratory volatility and field volatility.* EPA proposed to expand the data requirement for photodegradation in air adding all terrestrial, greenhouse, forestry and residential outdoor use patterns. The Agency's rationale relates to the potential for exposure to highly volatile pesticides in greenhouses, residential and certain outdoor use situations. The Agency received three comments on the expansion of the use patterns for this data requirement, asking for additional guidance on the conditions that would trigger this data requirement. EPA uses the measured vapor pressure of a chemical compound or the chemical's Henry's Law Constant, as guides to the chemical's volatility and the probability of its movement into the atmosphere. Pesticides with vapor pressures $\geq 3.9 \times 10^{-5}$ mm Hg are considered to be of intermediate to high volatility under field conditions and may become airborne and enter the environment [Ref. 7].

EPA received two comments on the test note for the photodegradation in water data requirement which provided values for the electronic absorption spectra for the pesticide at which the study is not required. One comment asked for more specific guidance regarding the absorbance of the hydrolysis mixture, and the other comment asked for clarification about the structural identities of the hydrolysis products. EPA believes the test note is clear, but the commenters detailed concerns that could be addressed on an individual basis.

EPA proposed to change the designation of the requirement for the photodegradation on soil study from conditionally required (CR) to required (R) for terrestrial food crop and forestry uses patterns. The Agency received one comment about this photodegradation requirement that questioned the proposed change in classification as stated in the proposed rule. EPA is codifying a long-standing practice of requiring this study for terrestrial and forestry use patterns. The test note explaining that the study is not required when the chemical is to be applied only by soil injection or is incorporated in the soil has been retained.

iii. *Aerobic soil and aerobic aquatic metabolism.* EPA proposed to expand the use patterns that require the aerobic soil metabolism study by including aquatic uses if the pesticide is applied to aquatic sites that are intermittently dry. The aerobic aquatic metabolism study requirements were expanded to include all terrestrial and forestry use patterns, and to clarify its requirement for aquatic residential use patterns. The Agency received five comments regarding the data requirements for the aerobic soil metabolism study and the aerobic aquatic metabolism study. The comments questioned the inclusion of aquatic use sites such as rice paddies and cranberry bogs that are intermittently dry for the soil metabolism study, and the inclusion of all terrestrial and forestry uses patterns for the aquatic metabolism study. They asked for further explanation of these changes. EPA categorizes uses such as cranberry bogs and rice paddies as aquatic, but such sites can be considered both aquatic and terrestrial depending on timing and agronomic practices. As explained in the proposed rule, both the aerobic aquatic and terrestrial studies are needed to better characterize the fate of chemicals applied to aquatic sites that are intermittently dry. Aquatic metabolism studies are needed for pesticides applied terrestrially since these chemicals can be transported, e.g., through run-off or spray drift, to water bodies. Since the degradation or dissipation rates and pathways of pesticides in aquatic systems can be different from those of terrestrial

systems, both soil metabolism and aquatic metabolism studies are needed to fully describe the fate of pesticides that may be found in both terrestrial and aquatic environments. In addition to being useful for developing ecological risk assessments, this study is also valuable in refining drinking water exposure estimates.

iv. *Anaerobic soil and anaerobic aquatic metabolism*. EPA proposed to correct a technical error in current part 158 by reinstating the requirement for the anaerobic soil metabolism study. The requirement appeared in 40 CFR 158.290 prior to 1991, but a simple printing error led to its omission from the CFR in 1991 and subsequent CFRs. The twelve comments that the Agency received about the anaerobic metabolism studies generally asserted that the anaerobic soil metabolism requirement in the proposed rule constituted a new data requirement. This data requirement was never intentionally removed from the CFR by notice and comment rulemaking, and therefore is not considered a new requirement.

EPA has continued to require the anaerobic soil study as needed, notwithstanding its inadvertent omission from the CFR, but has also upon occasion accepted the anaerobic aquatic study in lieu of the anaerobic soil study. However, with the harmonization of the OPP environmental fate guidelines with those of the OECD and with PMRA under NAFTA agreements, and with the technical correction and clarification of the requirements in this rule, this practice of substituting the anaerobic aquatic study is no longer appropriate. In the harmonized guidelines, the two studies use different test media and redox conditions, so the results of these two studies will not necessarily be comparable. Continuing to use the anaerobic aquatic study when the Agency requires the anaerobic soil study will not fully address Agency risk assessment needs.

The commenters were also concerned about the expansion of the anaerobic aquatic metabolism requirement to include all terrestrial use patterns, such that the applicants would be required to conduct two anaerobic studies. This added requirement, in their estimate, would have a significant impact, doubling the time of the anaerobic system requirement. With this rule EPA now requires both anaerobic studies for terrestrial uses where the pesticide is likely to move from the site of application to nearby aquatic systems. Since the degradation or dissipation rates and pathways of pesticides in aquatic systems can be different from those of terrestrial systems, soil metabolism studies alone may not be adequate to cover these terrestrial use patterns.

v. *Soil mobility*. EPA did not propose any changes to the data requirement for soil mobility studies. However, the Agency received three comments asking for clarification about which test type we prefer to fulfill this data requirement. Therefore, in the final rule, we added a new test note for the leaching and absorption/desorption data requirement that explains which test procedure is preferred.

vi. *Terrestrial, aquatic and forestry field dissipation studies*. EPA proposed to expand the use patterns that require the terrestrial field dissipation study to include aquatic food crops and aquatic nonfood uses when the pesticide is applied to aquatic sites that are intermittently dry (rice and cranberries were given as examples). Likewise, EPA proposed to expand the requirement for an aquatic field dissipation study from solely aquatic use patterns to conditionally include terrestrial use patterns as well. The third change the Agency proposed with the field dissipation studies was to merge the long-term field dissipation study into the terrestrial field dissipation study. Instead of a separate long-term study, the field dissipation study would be extended in duration for persistent pesticides to characterize their decline curves. A number of commenters were very concerned about the changes in the conditions and requirements for the dissipation studies. One issue raised by several commenters pertained to the likelihood that some chemicals and use patterns would now require two separate field dissipation studies instead of just one, as was the policy in the past. Several of the commenters asked for greater justification and clarification of the test notes from the Agency to explain the expansion of the data requirements. They also asked for additional guidance on the triggers and endpoints of the long-term study.

EPA acknowledges that some pesticides, based on their environmental fate profile and uses, may require both the aquatic and the terrestrial field dissipation studies, but we estimated that the frequency of this occurring is low. The Agency expanded the terrestrial field dissipation data requirement to gain a better understanding of the patterns of a pesticide's fate and transport when applied to crops that grow in both flooded and dry conditions in one growing season. This decision was endorsed by the FIFRA SAP in 1994. The data provided by the aquatic field study for terrestrial applications will provide data necessary to understand the fate of a terrestrially applied pesticide that has a high potential to enter aquatic environments. Data from these studies can reduce potential overestimation of exposure and risk and can confirm assumptions of low levels of toxic degradates. The test note for the aquatic study is based on harmonized language with PMRA under NAFTA, and provides the details that must be considered to determine if an aquatic (sediment) dissipation study is necessary for a terrestrial use.

One commenter recommended that to be consistent with the terrestrial field dissipation data requirement, the Agency should state that aquatic food crops, like rice and cranberry uses, which are managed to have a dry-land period for production, now must be conducted under the Terrestrial Field Dissipation (TFD) requirement. EPA agrees with this comment and has amended the test note for this study. The TFD guideline is available on the websites of EPA and PMRA.

EPA changed the requirement for the forestry dissipation study from required to conditionally required for pesticides used in forests. The Agency received five comments expressing the concern that with this change it is no longer clear what conditions of pesticide use in forestry would trigger this requirement. The Agency made the change because these studies are very difficult to conduct and very difficult to interpret. The trend over the past few years has been to rely on the terrestrial field dissipation studies for forestry uses. If this terrestrial dissipation study cannot assess all of the major routes of dissipation, the forestry study will be required.

The Agency did not propose any changes in the requirement for a field dissipation study for combination and tank mixes. Three comments identified the test note for this study as vague and with no useful information. They suggested that the test note be revised to clarify when this data requirement is needed, and the relevance of this data. EPA took their recommendation and rewrote this test note to clarify that this study may be triggered if there is specific evidence that the presence of one pesticide can affect the dissipation characteristics of another pesticide when applied simultaneously or serially.

vii. *Accumulation studies*. EPA proposed to change the conditions under which the accumulation in fish and accumulation in aquatic organisms would be required. EPA received eight

comments regarding the fish and nontarget organism accumulation studies. Three of the commenters suggested that this data requirement be placed in proposed subpart E (now subpart G), Terrestrial and Aquatic Nontarget Organism Data Requirements, and not subpart N. There were two comments stating that test note 10 was well written, and should also apply to the aquatic nontarget organism accumulation study requirement in lieu of test note 11, in the environmental fate data table. They suggested that this test note is also appropriate for the three accumulation studies in proposed subpart E, bioavailability, biomagnification and toxicity of aquatic organisms.

The Agency agrees with the comments, and moved the two studies under proposed subpart N, Accumulation in Fish and Accumulation in Aquatic Nontarget Organisms to subpart G, under the data requirement for aquatic organisms - bioavailability, biomagnification and toxicity. Therefore, all the ecological and fate requirements related to bioaccumulation are located solely in subpart G. We also agree with the comment that the language of Note 10 (Accumulation in Fish) in the proposed environmental fate data table is appropriate for the Accumulation in aquatic nontarget organisms data requirement in subpart G. Test note 10, ''Not required when the octanol/water partition coefficients of the pesticide and its major degradates are less than 1,000; or there are no potential exposures to fish and other nontarget aquatic organisms; or the hydrolytic half-life is less than 5 days at pH 5, 7, and 9.'' was moved to subpart G and renumbered as test note 19. This test note replaces draft test note 21 in proposed subpart E (now G).

viii. *Ground water monitoring.* EPA proposed to conditionally require a groundwater monitoring study for all terrestrial and forestry uses. EPA received six comments on the proposed new data requirement for ground water monitoring. This study is conditionally required for all terrestrial uses patterns and all forestry uses patterns. Because of the newness of this data requirement we received several comments questioning the conditions that would trigger this requirement. Three additional commenters asked for better guidance in the test note for this requirement. One of the commenters additionally expressed the opinion that the conditions in the test note for this study should focus on the results of the field dissipation studies rather than laboratory studies. The Agency affirms that the conditions described in the test note include both laboratory and field data, but points out that this test note also describes many factors that must be considered to determine if this requirement is triggered. It is quite complex and difficult to fully explain all possible scenarios that could trigger a groundwater monitoring study. In summary, EPA uses a weight-of-evidence approach that incorporates the results of the other environmental fate studies plus use patterns along with factors specific to the pesticide of concern.

In addition to these use patterns, one commenter recommended that the ground water monitoring data requirement be conditionally required (CR) for residential outdoor uses. We agree that there may be certain cases where a ground water monitoring study would be needed to inform a risk management decision for residential outdoor use pesticides. In the final rule, EPA made this study CR, but we expect that the need for this study is likely to be rare.

ix. *Degradates.* EPA received six comments regarding the need and potential triggers to test degradate substances in the laboratory studies. They all asked for clarification of the potential requirement. The Agency does not require degradate substances to undergo the set of fate data requirements as it requires of the active ingredients. The set of fate studies as currently designed and conducted with the TGAI provide adequate information on the formation, decline and mobility of the major degradates. Testing with degradates as the primary test substance is not required for the environmental fate data requirements.

XV. Discussion of Key Comments on Residue Chemistry Data Requirements (Subpart O)

EPA proposed codifying the residue chemistry data requirements that have arisen since the 1984 regulations were issued and clarifying and simplifying the 1984 data requirements. EPA has responded to comments in its Response to Comments document in the docket for this rule.

Some commenters viewed the proposed residential outdoor use pattern as an expansion of requirements for home garden uses and believed such uses do not fall under the scope of the FFDCA. EPA did not intend to expand the data requirement for residential uses; the current practice is to require data based on residential use only if the corresponding agricultural use on that crop is not approved or if the residential use is likely to have higher residues based on increased application rates or shorter preharvest intervals. EPA agrees that FFDCA does not apply to commodities that are not introduced into interstate commerce and tolerances are not established for residues on home garden crops. EPA does assess under FIFRA whether any adverse effects (e.g. dietary risks) could occur.

Some commenters requested a definition of indoor food use. EPA considers indoor food uses to be primarily pesticide treatment in food areas of food handling establishments (FHEs). FHEs include food servicing, food manufacturing, and food processing. Crack, crevice and space treatments are examples of application areas where pests hide or through which they enter a building. The FHE uses described above fall under the auspices of FFDCA and generally require residue data and tolerances (or exemptions from tolerances) for residues of conventional pesticides in food.

1. *Tolerances and tolerance exemptions.* A commenter requested a more complete definition of tolerance because the proposed definition implies that all the data requirements apply to applications for a tolerance exemption. EPA agrees with the commenter that the proposed rule implies that all the residue chemistry data requirements and conditions apply to tolerance exemptions, which is not the case. In many instances such data are not needed for an exemption due to the low toxicity of the pesticide or the ability to make a safety finding using theoretical dietary exposure estimates. The Agency added Test Note 25 to most of the data requirements to clarify when a residue chemistry data requirement may not be required for an exemption from a tolerance.

2. *Storage stability.* EPA proposed separately identifying the requirement to validate the Magnitude of the Residue studies. Commenters believed that requiring an explicit storage stability study was too rigid and suggested the registrant retain the option to include this data in a stand-alone report or in the magnitude of residue (MOR) report. As explained in the proposed rule, the separation of the storage stability regime was intended solely to give visibility to a requirement often overlooked in the residue studies. The Agency would not object to the storage stability data being in the MOR report in cases where the data were actually generated concurrently as part of the MOR study.

3. *Multiresidue methods.* There were no comments on the proposed codification of the multiresidue methods data requirement as a separate requirement; multiresidue methodology

data are currently part of the Residue Analytical Method requirement.

4. *Nature of the residue in livestock*. A commenter questioned EPA's basis for requiring this study when residues are not found in livestock feed. The primary reason for requiring the livestock metabolism study when measurable residues are not found on feed items from labeled uses is to assess the potential bioconcentration of the pesticides and metabolites of concern in animal products. Although residues in feed may not be quantifiable, EPA needs assurance that residues do not concentrate to measurable levels when livestock ingest the treated feeds.

5. *Residue analytical methods*. EPA proposed changing the test substance from TGAI and metabolites to residue of concern and proposed requiring an ILV; the latter is a policy that has been in place since 1988. Commenters varied on the value of the ILV of tolerance enforcement methods. EPA believes that the ILV requirement helps ensure that methods are clearly written and include detailed descriptions of all necessary steps. Due to resource limitations, EPA chemists can validate only a limited number of methods so the Agency relies greatly on the ILV as part of the review process to determine whether an adequate tolerance enforcement method is available.

A commenter felt that it would be appropriate to address radiovalidation under both the Nature of the Residue and the Analytical Method entries. While EPA views radiovalidation as an element of the Analytical method requirement, EPA believes the issue may be addressed in either the metabolism study report or the method validation report. Radiovalidation would not be necessary when the extraction procedures in the method and metabolism studies are identical or very similar and the metabolism study was deemed acceptable in terms of the levels of residues extracted and characterized/identified.

6. *Magnitude of the residue in processed food and feed, potable water, fish, and irrigated crops*. EPA proposed changing the test substance from EP to TEP because it believes that, in general, variations of the formulation will not affect the behavior of the active ingredient. Commenters believed that changing the test substance from EP to TEP would cause an increase in the residue data as each formulation type would need to be tested. EPA notes that the existing EP requirement from the 1984 rule would require residue data for each end-use product if it were to be implemented. In actual practice, EPA has been administratively following a TEP-based approach of grouping EPs into formulation classes that requires considerably less data than an EP approach. The rule revision merely codifies this current practice.

7. *Magnitude of the residue in meat, milk, poultry, and eggs*. A verbal request for clarification at the May 3–4, 2005, workshop on the proposed rule prompted EPA review of the test note pertaining to the nature of the residue in livestock. As a result, the test note was revised to indicate that data are required if pesticide residue are present in or on livestock feed items or intentionally added to drinking water. These studies may not be required if the metabolism studies show negligible transfer of the residues of concern at the maximum expected exposure.

A commenter questioned the necessity of conducting separate feeding studies for separate metabolites. Only when the chemical structure of the plant metabolite raises concerns over potential bioconcentration and/or increased toxicity would EPA require additional animal studies dosing with the plant metabolite. The study is rarely requested, but EPA prefers to maintain the proposed test substance and footnote to alert applicants to the possibility of such data.

8. *Confined and field rotational crops*. EPA proposed moving the data requirements for confined and field rotational crops from an environmental fate requirement to residue chemistry requirement since these are primarily a dietary risk assessment concern. Commenters suggested EPA describe in detail the triggers for progressing to the Tier II and Tier III studies and explain the data needed to establish tolerances for inadvertent residues in rotational crops. Upon further consideration, Test Notes 7 and 23 were revised to put the focus on residue uptake in rotational crops as opposed to residues in food. In addition, Test Note 24 was added to the crop field trial study to address situations where tolerances are needed on rotational crops.

XVI. Discussion of Data Requirements Not Affected by this Final Rule

This final rule does not apply to the data requirements for the registration of: biochemical pesticide products; microbial pesticide products; or antimicrobial pesticide products. EPA proposed to limit the applicability of revised part 158 to conventional pesticides in anticipation of additional revisions tailored to biochemical, microbial, and antimicrobial pesticides. Elsewhere in today's **Federal Register**, EPA is promulgating a final rule establishing data requirements for biochemical and microbial pesticides. For a discussion of the applicability of part 158 data requirements to antimicrobial pesticides, see Unit II.C. One commenter believed that the promulgation of data requirements for antimicrobial pesticides should precede the promulgation of data requirements for conventional pesticides. Because EPA believes that a revised part 158 provides an important and crucial framework for the other types of pesticides, EPA is adopting its proposal to limit the applicability of revised part 158 to conventional chemicals.

EPA has transferred the contents of the sections that were not addressed in the proposal essentially unchanged into the revised part 158, i.e., spray drift (subpart L) and product performance (subpart E). The regulatory text of the sections for which no changes were proposed is reprinted in this final rule for clarity and completeness.

XVII. Discussion of Key Comments on International Harmonization of Data Requirements

The preamble to the proposed rule discussed the Agency's extensive consultation and harmonization efforts with Canada and the OECD. Both the Pest Management Regulatory Agency (PMRA) and the EU submitted comments in response to the Agency's proposed rule. Both provided extensive comparisons of data requirements between the United States and their respective requirements. The PMRA stated that, in virtually every scientific discipline, the requirements exhibit a high degree of harmonization with the Canadian requirements. The EU, whose comments were based on their draft data requirements, noted that the U.S. requirements are not completely compatible with the corresponding EU data requirements. Nonetheless, the data requirements of the United States and the EU are comparable in many cases, with some exceptions. Both PMRA and the EU highlighted areas where continued collaboration toward development of a common testing strategy would be useful. EPA will continue to work with Canada and the EU through the OECD to harmonize data requirements, testing protocols and methodologies, and to promote work-sharing opportunities.

XVIII. Discussion of Key Comments on Animal Welfare Concerns

EPA received 53 comments, primarily from individuals, supporting its proposal to eliminate the 1–year dog study from the core toxicology data requirements and urging increased minimization of animal testing,

adoption of alternative non-animal testing, and revision of test strategies to incorporate innovations such as the one developed by ILSI/HESI.

The Agency is committed to avoiding unnecessary animal testing while taking into consideration principles of sound science and the requirements of FIFRA to protect humans and the environment. For example, chemicals with a demonstrated pH indicating a strongly acidic or alkaline substance need not be tested in animals to screen for eye or skin corrosivity potential. EPA will consider data from a validated *in vitro* corrosivity assay as a screen to judge whether a chemical may be corrosive to the eye or skin. Making this determination may reduce or avoid subsequent actual testing on animals. EPA is considering how the number of longer term studies might be reduced by examining the possibility to combine toxicological endpoints from more than one study. The Agency already has bridging and batching policies in place to allow the use of acute toxicity, sensitization, or irritation test data on products to be used to support other products.

EPA is working closely with 15 other U.S. agencies to advance the validation and adoption of alternative test methods through the Federal Interagency Coordinating Committee on Validation of Alternative Methods (ICCVAM) (http://iccvam.niehs.nih.gov), established by the National Institute of Environmental Health Sciences. ICCVAM works towards:

1. Encouraging the reduction of the number of animals used in testing, where possible.

2. Seeking opportunities to replace test methods requiring animals with alternative test methods when validated acceptable alternative methods are available.

3. Optimizing animal use by test method refinement.

ICCVAM, together with the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), convenes independent peer review panels, as appropriate, to evaluate the validation status of proposed test methods and coordinates expert panel meetings or workshops for validation or test method-related activities. ICCVAM has developed guidelines for the nomination and submission of new, revised, and alternative test methods (http://iccvam.niehs.nih.gov/SuppDocs/submission.htm).

The Agency has also co-sponsored a number of major workshops to advance alternative test method activities. EPA, ICCVAM, and NICEATM collaborated in the development of performance standard concepts for validated alternative tests (May 2004 NIH Publication No. 04–4510 [Ref. 6]. Recently, at the request of EPA, ICCVAM/NICEATM coordinated the review of four *in vitro* test methods for identifying ocular corrosives and severe irritants. EPA is incorporating new alternative tests and testing strategies into its programs to reduce animal use (e.g. in assessing acute oral toxicity [guideline 870.1000 revised and 870.1100 revised], dermal sensitization [guideline 870.2600 revised], and dermal irritation/corrosion).

The Agency also recognizes the need for timely periodic review, revision and/or supplementation, as applicable, of its test guidelines. As new tests and test batteries are validated, the Agency can present them to the FIFRA SAP to review their applicability in meeting regulatory needs. EPA can seek comment from the SAP on test guideline or other test method-related issues, depending on the circumstances. As other appropriate alternative or *in vitro* methods become available, they will be considered for addition to the Agency's test guidelines.

Finally, the Agency is committed to a more hypothesis-based testing paradigm by advancing *in silico, in vitro*, and efficient focused *in vivo* testing so that chemicals are tested in animals for those endpoints most relevant to each chemical's exposure or intended use. The Agency acknowledges that substantial work remains to achieve this long term goal, but the Agency is also working on the important short-term goal to make the existing animal testing paradigm more efficient, reliable, and responsive to its risk assessment and management needs. The Agency has undertaken several activities to move towards a more efficient animal paradigm, including analyzing and updating the current data requirements. As evidenced by this final rule, the Agency has completed its analysis of dog toxicity studies and determined that the 1–year dog study can now be omitted as a core data requirement for pesticides.

EPA is committed to revise part 158 data requirements to incorporate new science. In the meantime, the existing regulations provide flexibility to implement any updated, new or novel testing schemes, on a case-by-case basis, as appropriate, until the changes are codified.

XIX. Water Quality Issues

EPA received comments from four California water treatment authorities and two California cities' environmental agencies. The comments centered on their strong recommendations that FIFRA data requirements meet the needs of the Clean Water Act (CWA) regulatory program and should consider urban water quality issues. California water-treatment authorities questioned the adequacy of the Agency's assessment of risks with regard to water quality considerations including: use of aquatic toxicity data, surface water quality studies, and urban uses of pesticides, particularly when these uses result in pesticide residues in receiving waters from storm sewers or sewage treatment plants.

The goal of the 158 data requirements is to require the registrants to submit scientifically sound data, conducted according to recommended guidelines to enable the scientists in the Pesticide Program to conduct ecological risk assessments on a national scale. EPA believes the 158 data requirements are sufficient to conduct high quality risk assessments. EPA's evaluation and registration of pesticides under FIFRA take into account impacts on the aquatic environment. Also, under FIFRA, EPA has the authority to impose a specific restriction on the use of a pesticide in a particular geographic location. Such a restriction will appear in or be referenced on the labeling of all products distributed anywhere in the United States, but will affect the use of the pesticide only when it occurs within the identified geographic area. Although EPA has not routinely imposed labeling restrictions on pesticides to prevent degradation of high quality water, it could do so. As part of its reregistration and registration review programs, EPA's Pesticide and Water Offices are working more closely together to identify sites where water quality standards are not being met as a result of the presence of unacceptable levels of pesticide residues, and the Pesticide Office considers those issues in its reviews. OPP provides State and Tribal pesticide lead agencies with water quality grant funds in order to develop and carry out management programs to protect ground and surface water resources from pesticide risks.

XX. Endangered Species

Incidental to its proposed data requirements for conventional pesticides, EPA discussed the possibility of future data and information needs to develop and/or refine risk assessments for endangered species. EPA did not propose any data requirements specific to endangered species, but described its current level of information and data usage. EPA requested comment on the value and

utility of location and usage information, and on additional types of research that might yield greater refinement in risk assessments for endangered species.

EPA appreciates the response it received from commenters on these topics, primarily from industry task forces and associations. As endangered species data requirements were not proposed, EPA has not responded to the comments as part of this final rule, but will consider them in the context of its ongoing risk assessments. If EPA finds that it needs to amend part 158 to normalize endangered species data requirements, it will consider these comments in the development of a future proposed rule.

XXI. Implementation

After the effective date, the data requirements in this final rule will apply to all new registrations of conventional pesticides. The Agency does not intend to apply these requirements retroactively to all existing pesticide registrations, but the Agency may find it necessary to call in some data on certain existing registrations, as warranted by emerging risks of concern on particular pesticides or as a result of possible programmatic changes and priorities on existing pesticides. FIFRA sec. 3(c)(2) provides EPA broad authority, before and after registration, to require scientific testing and submission of the resulting data to the Agency by registrants and applicants of pesticide products. Although the data requirements in part 158 are imposed primarily as a part of initial registration, EPA is authorized under FIFRA sec. 3(c)(2)(B) to require a registrant to develop and submit additional data necessary to maintain a registration. This post-registration data call-in authority recognizes that the scientific underpinnings of risk assessment change, and is another means by which EPA may keep data for use in risk assessment current with evolving science.

EPA will consider as part of its review of a pending application whether and how to apply these updated data requirements. EPA expects that few changes will be needed, as these updated requirements reflect current practice.

Some commenters believed the revised data requirements in 40 CFR part 158 had to be finalized before registration review could be implemented. While the part 158 data requirements and registration review are related, they are not inextricably linked but rather proceed along parallel tracks. The Agency makes case-by-case data determinations as standard program practice so the registration review program now being implemented can operate effectively in the absence of updated data requirements. The updated data requirements in this final rule will provide applicants with more clarity and transparency in the information presented in part 158.

XXII. References

The Agency established an official docket for this rulemaking under Docket ID No. OPP–2004–0387. All of the documents that have been included in that docket are available at http://www.fdms.gov. The following is a list of the documents that are specifically referenced in this final rule. Not all docket materials are available electronically but all publicly available docket materials are available through the Docket facility described under **ADDRESSES**.

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2. Carmichael, N.G., Barton, H.A., Boobis, A.R., Cooper, R.L., Dellarco, V.L., Doerrer, N.G., Fenner-Crisp, P.A., Doe, J.E., Lamb, J.C., and Pastoor, T.P. Agricultural chemical safety assessment: a multi-sector approach to the modernization of human safety requirements. January 2006. *Critical Reviews in Toxicology*. v. 36, 1–7.

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6. Interagency Coordinating Committee on the Validation of Alternative Methods and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods. Recommended Performance Standards for *In Vitro* Test Methods for Skin Corrosion. NIH Publication No. 04–4510. May 2004. *http://iccvam.niehs.nih.gov/dermal/epiderm/ps/ps044510.pdf*.

7. Kennedy, J.M. and Talbert, R.E. Comparative persistence of dinitroaniline-type herbicides on the soil surface. 1977. *Weed Science*, v. 25(5), 373–381.

8. Mineau, P., Baril, A., Collins, B.T., Duffe, J., Joerman, G. and Luttik, R. Pesticide acute toxicity reference values for birds. 2001. *Review of Environmental and Contamination Toxicology*, v. 170, 13-74.

9. Schafer, E.W. and Brunton, R.B. Indicator bird species for toxicity determinations: is the technique usable in test method development? 1979. Vertebrate Pest Control and Management Materials (American Society for Testing and Materials Special Technical Publication 680), pp. 157-168.

10. U.S. Environmental Protection Agency. A Comparison of the Results of Studies on Pesticides from 1– or 2–Year Dog Studies with Dog Studies of Shorter Duration; a set of scientific issues being considered by the EPA, May 5 and 6, 2005, FIFRA Scientific Advisory Panel Meeting, held at the Holiday Inn-Rosslyn at Key Bridge, Arlington, Virginia. Washington, DC: U.S. Environmental Protection Agency. May 2005.

11. U.S. Environmental Protection Agency. Economic Analysis of the Change in the Data Requirements Rule for Conventional Pesticides. Washington, DC: Biological and Economic Analysis Division, Office of Pesticide Programs, U.S. Environmental Protection Agency. November 7, 2006.

12. U.S. Environmental Protection Agency. Length of Dog Toxicity Study(ies) that is Appropriate for Chronic RfD Determinations of Pesticide Chemicals. Washington, DC: Health Effects Division, Office of Pesticide Programs, U.S. Environmental Protection Agency. March 20, 2006.

13. U.S. Geological Survey. Pesticides in stream sediment and aquatic biota: current understanding of distribution

and major influences. (Fact Sheet 092–00) August 24, 2000. *http://ca.water.usgs.gov/pnsp/rep/fs09200/*.

14. Letter from Dr. Maurice Zeeman, U.S. National Coordinator, OECD Test Guidelines Program, to Dr. Eisaku Toda, Environment, Health, and Safety Division, OECD/Environment Directorate, regarding the U.S. comments received in response to requested review of the proposed OECD Test Guideline 223: Avian Acute Oral Toxicity Test. March 24, 2003.

XXIII. FIFRA Review Requirements

In accordance with FIFRA sec. 25(a), a draft of this final rule was submitted to the FIFRA SAP, the Secretary of Agriculture and appropriate Congressional Committees. The FIFRA SAP waived its review of this final rule because the significant scientific issues involved have already been reviewed by the SAP and additional review isn't necessary.

XXIV. Statutory and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this action is a significant regulatory action because it might raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted this action to OMB for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action as required by sec. 6(a)(3)(E) of the Executive Order.

In addition, EPA prepared an analysis of the potential costs and benefits associated with this action, entitled ''Economic Analysis of the Changes in the Data Requirements Rule for Conventional Pesticides'' [Ref. 11]. A copy of the analysis is available in the docket for this action.

This final rule is similar to the proposed rule except that some data requirements will no longer be required. As such, the estimated annual cost of this final rule will be less than the estimated annual cost of the proposed rule. The estimated costs for the data requirements that will no longer be required are:

1. *Chronic oral-non-rodent*. This test was required as part of the baseline requirements. The cost of this test is approximately $950,000 and was recently required an average of almost 18 times per year for the entire industry. Since this test will no longer be required, the estimated cost of this rule decreased from the proposed estimate by almost $16.6 million per year.

2. *Special toxicity tests*. Three special toxicity tests, which were expected to be required about 1% of the time, will no longer be required. These tests are:

- Scheduled Controlled Operant Behavior,
- Peripheral Nerve Function,
- Neurophysiology: Sensory Evoked Potentials.

In addition, some of the test notes associated with the Ecological Effects data requirements have been revised. These revisions will slightly reduce the percent of time these data requirements may be imposed, resulting in a slight reduction of the cost of the rule. However, these costs were not re-estimated because of the expected minimal impact. As a result of these changes, the estimated annual incremental cost of the final rule is expected to be about $33.6 million for the industry. The elimination of the toxicity tests as described above reduces the estimated cost of the rule by almost $17 million.

This cost reduction also applies to the high-cost option (require data 100% of the time). The low-cost option (codification of current practice) is the same in the proposed and final rule. It is no longer the lowest cost option under the final rule because current practice retains the data requirements that were eliminated in the final rule. Since the expected overall impact of this final rule on businesses is expected to be small, the Agency believes that the effect on the availability of pesticides to users is not likely a deleterious one. On balance, the Agency believes that the cost of the rule is justified by the benefits from the enhanced protection of human health and the environment.

B. Paperwork Reduction Act

The information collection activities related to the submission of data to EPA in order to register a conventional pesticide product are already approved by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq. This action does not impose any new information collection burden. The information collection activities are already approved by OMB under the following existing ICRs:

1. The activities associated with the establishment of a tolerance are currently approved under OMB Control No. 2070–0024 (EPA ICR No. 0597);

2. The activities associated with the application for a new or amended registration of a pesticide are currently approved under OMB Control No. 2070–0060 (EPA ICR No. 0277);

3. The activities associated with the generation of data for reregistration are currently approved under OMB Control No. 2070– 0107 (EPA ICR No. 1504); and

4. The activities associated with the generation of data for experimental use permits are currently approved under OMB Control No. 2070–0040 (EPA ICR No. 0276).

Copies of these OMB-approved Information Collection Request (ICR) may be obtained from Susan Auby, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW, Washington, DC 20460 or by calling (202) 566–1672.

Under the PRA, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes 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, or is otherwise required to submit the specific information by a statute. The OMB control numbers for EPA's regulations codified in Title 40 of the Code of Federal Regulations, after appearing in the preamble of the final rule, are further displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in a list at 40 CFR 9.1.

For the ICR activity contained in this final rule, in addition to displaying the applicable OMB control number in this Unit, the Agency is amending the table in 40 CFR 9.1 to list the OMB control number assigned to the collection activities in this rulemaking. Due to the technical nature of the table, EPA finds that further notice and comment about amending the table is unnecessary. As a result, EPA finds that there is good

cause under section 553(b)(B) of the Administrative Procedures Act (APA), 5 U.S.C. 553(b)(B), to amend the table in 40 CFR 9.1 without further notice and comment.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility (RFA), 5 U.S.C. 601 et seq., the Agency hereby certifies that this rule will not have a significant adverse economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) a small business engaged in the manufacture of pesticide and other agricultural chemicals with 500 employees or fewer as defined by NAIC code 325320; (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. EPA has determined that this final rule does not impact any small governmental jurisdictions or any small not-for-profit enterprise because these entities are rarely pesticide applicants or registrants. The small entities directly regulated by this final rule are small manufacturers of pesticides and other agricultural chemicals.

Since the expected incremental cost of the final rule is about $33.6 million, which is about 33% less (almost 17 million less) than what was estimated for the proposed rule, the potential impacts on small businesses in the final rule would be less than what was estimated for the proposed rule. The small business impacts for the final rule were not re-estimated since they were not significant under the proposed rule and will therefore be even less significant under the final rule.

Based on the Economic Analysis for the proposed rule, of the 61 firms that might be impacted by this final rule, EPA had estimated that 2.4% are likely to experience a cost increase of 1% or more of gross sales. A cost increase of 3% or more of gross sales is expected to be experienced by 1.6% of the potentially impacted small firms.

Although this final rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. EPA believes that the users most in need of clarity are the infrequent, generally small applicants, whose data requirements are in many cases limited to enduse product data of various types. Smaller follow-on or me-too registrants are often required to generate only product-specific chemistry data, acute toxicity data, and efficacy data. These applicants will benefit by the restructured part 158 so they don't have to search for applicable data requirements by sifting through voluminous data requirements that may be satisfied by the formulators' exemption, citation, or offer-to-pay procedures. EPA has restructured the subparts to place the data requirements applicable to the bulk of applications (new end-use and me-too products) towards the beginning of part 158 to make the regulation more user-friendly.

D. Unfunded Mandates Reform Act

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, EPA has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local or tribal governments, in the aggregate, or on the private sector in any 1 year. The annual costs associated with this action are estimated to total about $33.6 million to applicants and registrants. These costs represent the incremental costs due to the additional or modified data requirements contained in this action. Since State, local, and tribal governments are rarely pesticide applicants or registrants, this rule is not expected to affect small governments. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132

Under Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that 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. Since States or local governments are rarely pesticide applicants or registrants, this final rule may seldom affect a State or local government. Thus, Executive Order 13132 does not apply to this rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed rule from State and local officials. EPA did not receive comments on federalism. EPA did receive comments on substantive parts of the rule from State governments and these are addressed elsewhere.

F. Executive Order 13175

Under Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), EPA has concluded that this rule does not have tribal implications because it will not have any affect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Executive Order. At present, no tribal government holds, or has applied for, a pesticide registration. Thus, Executive Order 13175 does not apply to this rule.

G. 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 action because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This rule does not establish an environmental standard that will have a negatively disproportionate effect on children. This rule is intended to provide added protection for children from pesticide risk. EPA will use the data and information obtained by this action to carry out its mandate under FFDCA to give special attention to the risks of pesticides to sensitive subpopulations, especially infants and children.

H. Executive Order 13211

This rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because it is not designated as an ''economically significant'' regulatory action under Executive Order 12866, nor is it likely to have any adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 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 involves environmental monitoring or measurement. Consistent with the Agency's Performance Based Measurement System (PBMS), EPA has decided not to require the use of specific, prescribed analytic methods. Rather, the rule will allow the use of any methods that meets the prescribed performance criteria. The PBMS approach is intended to be more flexible and cost-effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the performance criteria specified.

J. Executive Order 12898

This rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency does not need to consider environmental justice-related issues.

XXV. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., 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 the 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).

List of Subjects in 40 CFR Part 9

Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 158

Environmental protection, Confidential business information, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 4, 2007.

Stephen L. Johnson,

Administrator.

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

PART 9—[AMENDED]

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 et seq., 136 136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601 2671; 21 U.S.C. 331j, 346a, 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971 1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g 1, 300g 2, 300g 3, 300g 4, 300g 5, 300g 6, 300j 1, 300j 2, 300j 3, 300j 4, 300j 9, 1857 et seq., 6901 6992k, 7401 7671q, 7542, 9601 9657, 11023, 11048.

■ 2. In § 9.1, the table is amended by revising the entries under the centerheading ''Data Requirements for Registration'' and by adding the centerheading ''Data Requirements for Registration of Antimicrobial Pesticides'' and its entries immediately before the existing centerheading ''State Registration of Pesticide Products.'' to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * * * *	
Data Requirements for Registration	
158.32	2070–0040, 2070–0053, 2070–0057, 2070–0060, 2070–0107
158.34	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.45	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.75	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.110	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.200	2070–0040
158.310	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.320	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.325	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.330	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.335	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.340	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.345	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.350	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.355	2070–0040, 2070–0057, 2070–0060, 2070–0107
158.400	2070–0057, 2070–0060, 2070–0107
158.500	2070–0057, 2070–0060, 2070–0107
158.630	2070–0057, 2070–0060, 2070–0107
158.660	2070–0057, 2070–0060, 2070–0107
158.630	2070–0057, 2070–0060, 2070–0107
158.1050	2070–0057, 2070–0060, 2070–0107
158.1100	2070–0057, 2070–0060, 2070–0107
158.1300	2070–0057, 2070–0060, 2070–0107
158.1410	2070–0057, 2070–0060, 2070–0107
158.2000	2070–0057, 2070–0060, 2070–0107

40 CFR citation	OMB control No.
158.2100	2070–0057, 2070–0060, 2070–0107
* * * * * * *	
Data Requirements for Registration of Antimicrobial Pesticides	
161.30	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.32	2070–0040, 2070–0053, 2070–0057, 2070–0060, 2070–0107
161.34	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.45	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.75	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.101	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.150	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.160	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.162	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.165	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.167	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.170	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.175	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.180	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.190	2070–0040, 2070–0057, 2070–0060, 2070–0107
161.240	2070–0057, 2070–0060, 2070–0107
161.290	2070–0057, 2070–0060, 2070–0107
161.340	2070–0057, 2070–0060, 2070–0107
161.390	2070–0057, 2070–0060, 2070–0107
161.440	2070–0057, 2070–0060, 2070–0107
161.490	2070–0057, 2070–0060, 2070–0107
161.540	2070–0057, 2070–0060, 2070–0107
161.590	2070–0057, 2070–0060, 2070–0107
161.640	2070–0057, 2070–0060, 2070–0107
161.740	2070–0057, 2070–0060, 2070–0107
* * * * *	

■ 3. By adding new part 158 to read as follows:

PART 158—DATA REQUIREMENTS FOR PESTICIDES

Subpart A—General Provisions

Sec.
158.1 Purpose and scope.
158.3 Definitions.
158.5 Applicability.
158.30 Flexibility.
158.32 Format of data submissions.
158.33 Confidential data.
158.34 Flagging of studies for potential adverse effects.
158.45 Waivers.
158.60 Minor use data policies.
158.70 Satisfying data requirements.
158.75 Requirements for additional data.
158.80 Use of other data.

Subpart B—How to Use Data Tables

158.100 Pesticide use patterns.
158.110 Required and conditionally required data.
158.120 Determining data requirements.
158.130 Purposes of the registration data requirements.

Subpart C—Experimental Use Permits

158.200 Experimental use permit data requirements tables.
158.210 Experimental use permit data requirements for product chemistry
158.220 Experimental use permit data requirements for product performance.
158.230 Experimental use permit data requirements for toxicology.
158.240 Experimental use permit data requirements for ecological effects.
158.243 Experimental use permit data requirements for terrestrial and aquatic nontarget organisms.
158.250 Experimental use permit data requirements for human exposure.
158.260 Experimental use permit data requirements for environmental fate.
158.270 Experimental use permit data requirements for residue chemistry.
158.280 - 158.290 [Reserved]

Subpart D—Product Chemistry

158.300 Definitions.
158.310 Product chemistry data requirements table.
158.320 Product identity and composition.
158.325 Description of materials used to produce the product.
158.330 Description of production process.
158.335 Description of formulation process.
158.340 Discussion of formation of impurities.
158.345 Preliminary analysis.
158.350 Certified limits.
158.355 Enforcement analytical method.

Subpart E—Product Performance

158.400 Product performance data requirements.

Subpart F—Toxicology

158.500 Toxicology data requirements table.
158.510 Tiered testing options for nonfood pesticides.

Subpart G—Ecological Effects

158.630 Terrestrial and aquatic nontarget organisms data requirements table.
158.660 Nontarget plant protection data requirements table.

Subparts H–J [Reserved]

158.700 – 158.900 [Reserved]

Subpart K—Human Exposure

158.1000 Applicator exposure—general requirements.
158.1010 Applicator exposure—criteria for testing.
158.1020 Applicator exposure data requirements table.
158.1050 Post-application exposure—general requirements.
158.1060 Post-application exposure—criteria for testing.
158.1070 Post-application exposure data requirements table.

Subpart L—Spray Drift

158.1100 Spray drift data requirements table.

Subpart M [Reserved]

158.1200 – 158.1299 [Reserved]

Subpart N—Environmental Fate

158.1300 Environmental fate data requirements table.

Subpart O—Residue Chemistry

158.1400 Definitions.
158.1410 Residue chemistry data requirements table.

Subparts P–T [Reserved]

158.1500 - 158.1900 [Reserved]

Subpart U—Biochemical Pesticides [Reserved]

158.2000 [Reserved]

Subpart V—Microbial Pesticides [Reserved]

158.2100 [Reserved]

Subpart W—Antimicrobial Pesticides [Reserved]

158.2200 [Reserved]

Subpart X–Z [Reserved]

158.2300 - 158.2500 [Reserved]

Authority: 7 U.S.C. 136 - 136y; 21 U.S.C. 346a.

Subpart A—General Provisions

§ 158.1 Purpose and scope.

(a) *Purpose.* The purpose of this part is to specify the kinds of data and information EPA requires in order to make regulatory judgments under FIFRA secs. 3, 4, and 5 about the risks and benefits of pesticide products. Further, this part specifies the data and information needed to determine the safety of pesticide chemical residues under FFDCA sec. 408.

(b) *Scope.* (1) This part describes the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; support the reregistration of a pesticide product; support the maintenance of a pesticide registration by means of the data call-in process, e.g., as used in the registration review program; or establish or maintain a tolerance or exemption from the requirements of a tolerance for a pesticide chemical residue.

(2) This part establishes general policies and procedures associated with the submission of data in support of a pesticide regulatory action.

(3) This part does not include study protocols, methodology, or standards for conducting or reporting test results; nor does this part describe how the Agency uses or evaluates the data and information in its risk assessment and risk management decisions, or the regulatory determinations that may be based upon the data.

(c) *Scope of individual subparts.* (1) *Conventional pesticides.* Subparts A, B, C, D, F, G, K, L, N, and O apply to conventional pesticides.

(2) *Biochemical pesticides.* Subparts A, B and U apply to biochemical pesticides.

(3) *Microbial pesticides.* Subparts A, B and V apply to microbial pesticides.

(4) *Antimicrobial pesticides.* [Reserved]

§ 158.3 Definitions.

All terms defined in sec. 2 of the Federal Insecticide, Fungicide, and Rodenticide Act apply to this part and are used with the meaning given in the Act. Applicable terms from the Federal Food, Drug, and Cosmetic Act also apply to this part. Individual subparts may contain definitions that pertain solely to that subpart. The following additional terms apply to this part:

Applicant means any person or entity, including for the purposes of this part a registrant, who submits, or is required to submit, to the Agency any application, petition, or submission intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide. Such submissions may include, but are not limited to, the following:

(1) An application for registration or amended registration of a pesticide product under FIFRA sec. 3 or 24.

(2) A submission of data required in conjunction with reregistration of a currently registered product under FIFRA sec. 4.

(3) An application for an experimental use permit under FIFRA sec. 5.

(4) A submission of data in response to a notice issued by EPA under FIFRA sec. 3(c)(2)(B).

(5) A petition to establish or modify a tolerance or an exemption from the requirement of a tolerance for a pesticide chemical residue under FFDCA sec. 408.

Registration includes a new registration, amended registration and reregistration, unless stated otherwise.

§ 158.5 Applicability.

(a) The requirements of this part apply to the following submissions:

(1) An application for new or amended registration under FIFRA sec. 3 or 24.

(2) An application for experimental use permit under FIFRA sec. 5.

(3) A submission of data or information to support the continuation of a registration under FIFRA sec. 3, 4, or 24.

(4) A petition to establish, modify or revoke a tolerance or exemption from a tolerance under FFDCA sec. 408.

(b) The information specified in this part must be furnished with each submission described in paragraph (a) of this section if it has not been submitted previously, or if any previous submission is not accurate or complete.

§ 158.30 Flexibility.

(a) FIFRA provides EPA flexibility to require, or not require, data and information for the purposes of making regulatory judgments for pesticide products. EPA has the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. The Agency encourages each applicant to consult with EPA to discuss the data requirements particular to its product prior to and during the registration process.

(b) The Agency cautions applicants that the data routinely required in this part may not be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects to man or the environment. EPA may require the submission of additional data or information beyond that specified in this part if such data or information are needed to appropriately evaluate a pesticide product.

(c) This part will be updated as needed to reflect evolving program needs and advances in science.

§ 158.32 Format of data submissions.

(a) *General.* (1) All data submitted under this part must be formatted in accordance with this section.

(2) The requirements of this section do not apply to administrative materials accompanying a data submission, including forms, labeling, and correspondence.

(b) *Transmittal document.* Each submission in support of a regulatory action must be accompanied by a transmittal document, which includes:

(1) Identity of the submitter.

(2) The transmittal date.

(3) Identification of the regulatory action with which the submission is associated, *e.g.*, the registration or petition number.

(4) A list of the individual documents included in the submission.

(c) *Individual documents.* Unless otherwise specified by the Agency, each submission must be in the form of individual documents or studies. Previously submitted documents should not be resubmitted unless specifically requested by the Agency, but should be cited with adequate information to identify the previously submitted document. Each study or document should include the following:

(1) A title page including the following information:

(i) The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed.

(ii) The author(s) of the study.

(iii) The date the study was completed.

(iv) If the study was performed in a laboratory, the name and address of the laboratory, project numbers or other identifying codes.

(v) If the study is a commentary on or supplement to another previously

submitted study, full identification of the other study with which it should be associated in review.

(vi) If the study is a reprint of a published document, all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and date of publication.

(2) The appropriate statement(s) regarding any data confidentiality claims as described in § 158.33.

(3) A statement of compliance or non-compliance with respect to Good Laboratory Practice Standards as required by 40 CFR 160.12, if applicable.

(4) A complete and accurate English translation must be included for any information that is not in English.

(5) A flagging statement as prescribed by § 158.34, if applicable.

§ 158.33 Confidential data.

(a) *Definitions.* For the purposes of this section:

(1) *Registered or previously registered pesticide* means any pesticide containing an active ingredient contained in a product that is, or has ever been, an active ingredient in a product registered under sec. 3 of FIFRA. A registered pesticide that is the subject of an application for a new use falls within the category of ''registered or previously registered pesticide.''

(2) *Safety and efficacy information* means information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism.

(b) *Applicability.* (1) This section applies to information submitted pursuant to this part. It supplements the general confidentiality procedures in 40 CFR part 2, subpart B, including FIFRA confidentiality procedures at 40 CFR 2.307. To the extent that provisions in this section conflict with those in 40 CFR part 2, subpart B, the provisions in this section take precedence. The provisions of 40 CFR 2.308 do not apply to information to which this section applies. In addition to complying with the requirements of this section, any confidentiality claims for information subject to 40 CFR part 174 (plant-incorporated protectants) must be substantiated at the time of submission as described in § 174.9 of this chapter.

(2) FFDCA sec. 408(i) protects confidential information submitted in connection with an application for a tolerance or exemption to the same extent as FIFRA sec. 10. References in this section to FIFRA sec. 10 are deemed to apply equally to information submitted pursuant to FFDCA sec. 408, pursuant to the authority in sec. 408(i).

(c) *Method of asserting business confidentiality claims*—(1) *Claim required.* Information to which this section applies (and which is submitted on or after the effective date of this regulation) will be deemed as not subject to a confidentiality claim unless a claim for that information is made in accordance with the procedures specified in this paragraph. Information not subject to a confidentiality claim may be made available to the public without further notice, subject to the requirements of FIFRA sec. 10(g).

(2) *Statement required.* Upon submission to EPA, each document must be accompanied by a signed and dated document containing either the statements in paragraph (c)(2)(i) or (ii) of this section. No claims or markings on the document or any attachments, other than these statements and attachments submitted in accordance with paragraph (c)(3) of this section, will be recognized as asserting a claim of confidentiality. The format of data submissions is set forth in § 158.32.

(i) *No claim of confidentiality.*

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA sec. 10(g).

(ii) *Claim of confidentiality.*

Information claimed as confidential has been removed to a confidential attachment.

(3) *Confidential attachment.* (i) All information claimed as confidential must be submitted in a separate confidential attachment to the document and cross referenced to the specific location in the document from which it was removed. The confidential attachment must have its own title page and be paginated separately from the non-confidential document.

(ii) All information in the confidential attachment that consists of (or whose disclosure would in turn disclose) manufacturing or quality control processes must be individually identified in the confidential attachment as a claim for information within the scope of FIFRA sec. 10(d)(1)(A).

(iii) All information in the confidential attachment that consists of (or whose disclosure would in turn disclose) the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, must be individually identified in the confidential attachment as a claim for information within the scope of FIFRA sec. 10(d)(1)(B).

(iv) All information in the confidential attachment that consists of (or whose disclosure would in turn disclose) the identity or percentage quantity of any deliberately added inert ingredient of a pesticide must be individually identified in the confidential attachment as a claim for information within the scope of FIFRA sec. 10(d)(1)(C).

(v) Information in the confidential attachment that is designated in accordance with paragraphs (c)(3)(ii) - (iv) of this section must be on a separate page from information that is not so designated.

(4) *Voluntary release of information to States and foreign governments.* (i) Submitters are encouraged to include with the statement required under paragraph (c)(2) of this section an additional statement to allow EPA to share information with State and foreign governments. EPA will not consider such a statement to be a waiver of confidentiality or proprietary claims for the information. The statement is as follows:

I authorize the Environmental Protection Agency to release any information contained in this document to State or foreign governments, without relinquishing proprietary rights or any confidentiality claims asserted above.

(ii) Information designated as releasable to state or foreign governments in accordance with this section may be released to such a government without further notice to the submitter. EPA will inform the State or foreign government of any of the confidentiality claims associated with the information.

(d) *Release of information.* (1) Safety and efficacy information that was submitted to EPA on or after May 4, 1988 and that has not been designated by the submitter as FIFRA sec. 10(d)(1)(A), (B), or (C) information in accordance with the applicable requirements of this section is not entitled to confidential treatment and may be disclosed to the public without further notice to the submitter, in accordance with paragraph (d)(2) of this section. Safety and efficacy information

which has been designated by the submitter as FIFRA sec. 10(d)(1) (A), (B), or (C) information is entitled to confidential treatment only to the extent provided by FIFRA sec. 10(b), this section, and 40 CFR 2.208.

(2) Information that is not entitled to be protected as confidential in accordance with FIFRA sec. 10(b), this section and with EPA confidentiality regulations at 40 CFR part 2, subpart B, may be released to the public without the affirmation of non-multinational status provided under FIFRA sec. 10(g), provided that the information does not contain or consist of any complete unpublished report submitted to EPA, or excerpts or restatements of any such report which reveal the full methodology and complete results of the study, test, or experiment, and all explanatory information necessary to understand the methodology or interpret the results.

§ 158.34 Flagging of studies for potential adverse effects.

(a) Any applicant who submits a study of a type listed in paragraph (b) of this section must submit with the study a statement in accordance with paragraph (c) of this section.

(b) The following table indicates the study types and the criteria to be applied to each. Column 1 lists the study types by name. Column 2 lists the associated Pesticide Assessment Guideline number. Column 3 lists the criteria applicable to each type of study. Column 4 lists the reporting code to be included in the statement specified in paragraph (c) of this section when any criterion is met or exceeded.

TABLE—FLAGGING CRITERIA

Study Type(s)	Guideline No.	Criteria: Treated animals show any of the following:	Criteria No.
Carcinogenicity or combined carcinogenicity/ chronic feeding study	870.4200 870.4300	An incidence of neoplasms in males or females which increases with dose (positive trend p≤ 0.05); or	1
		A statistically significant (pairwise p≤ 0.05) increase of any type of neoplasm in any test group, males or females at any dose level, compared to concurrent control animals of the same sex; or	2
		An increase in any type of uncommon or rare neoplasms in any test group, males or females animals at any dose level, compared to concurrent controls of the same sex; or	3
		A decrease in the time to development of any type of neoplasms in any test group, males or females at any dose level, compared to concurrent controls of the same sex.	4
Prenatal developmental toxicity Reproduction and fertility Developmental neurotoxicity	870.3700 870.3800 870.6300	When compared to concurrent controls, treated offspring show a dose-related increase in malformations, pre- or post-natal deaths, or persistent functional or behavioral changes on a litter basis in the absence of significant maternal toxicity at the same dose level.	5
Neurotoxicity	870.6100 870.6200	When compared to concurrent controls, treated animals show a statistically or biologically significant increase in neuropathological lesions or persistent functional or behavioral changes.	6
Chronic feeding Carcinogenicity Reproduction and fertility Prenatal developmental toxicity Developmental neurotoxicity Acute or 90–day neurotoxicity	870.4100 870.4200 870.3800 870.3700 870.6300 870.6200	The no observed adverse effect level (NOAEL) from one of these studies is less than the NOAEL currently used by the Agency as the basis for either the acute or chronic reference dose.	7

(c) *Identification of studies.* For each study of a type identified in paragraph (b) of this section, the applicant shall include the appropriate one of the following two statements, together with the signature of the authorized representative of the company, and the date of signature:

(1) Study does not meet or exceed criteria.

I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.

(2) Study meets or exceeds criteria.

I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study meets or exceeds the criteria numbered [insert all applicable reporting codes].

§ 158.45 Waivers.

(a) The data requirements specified in this part as applicable to a category of products will not always be appropriate for every product in that category. Some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. The Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

(b)(1) Applicants are encouraged to discuss a data waiver request with the Agency before developing and submitting supporting data, information, or other materials.

(2) All waiver requests must be submitted to the Agency in writing. The request must clearly identify the data requirement(s) for which a waiver is sought along with an explanation and supporting rationale why the applicant

believes the data requirement should be waived. In addition, the applicant must describe any unsuccessful attempts to generate the required data, furnish any other information which the applicant(s) believe(s) would support the request, and when appropriate, suggest alternative means of obtaining data to address the concern which underlies the data requirement.

(c) The Agency will review each waiver request and subsequently inform the applicant in writing of its decision. If the decision could apply to more than the requested product, the Agency, in its discretion, may choose to send a notice to all registrants or publish a notice in the **Federal Register** announcing the decision. An Agency decision denying a written request to waive a data requirement is a final Agency action.

§ 158.60 Minor use data policies.

FIFRA sec. 2(ll) defines the term ''minor use''and FIFRA provides a number of statutory provisions concerning minor uses. In addition, EPA has established policies with respect to minor uses of pesticides, including, but not limited to, the following:

(a) A new data requirement pertinent to both an unregistered minor use and a registered major use will not be applied to a minor use applicant until it is applied to the major use registration.

(b) EPA will accept appropriate and adequate extrapolations and regional data to support establishment of individual minor use tolerances.

§ 158.70 Satisfying data requirements.

(a) *General policy.* The Agency will determine whether the data submitted or cited to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible. The Agency will not reject data merely because they were derived from studies which, when initiated, were in accordance with an Agency-recommended protocol, even if the Agency subsequently recommends a different protocol, as long as the data fulfill the purposes of the requirements as described in this paragraph.

(1) The provisions in this part 158 should be read in conjunction with the provisions in § 152.85 to claim eligibility for the formulators' exemption.

(2) [Reserved]

(b) *Good laboratory practices.* Applicants must adhere to the good laboratory practice (GLP) standards described in 40 CFR part 160 when conducting studies. Applicants must also adhere to GLP standards when conducting a study in support of a waiver request of any data requirement which is within the scope of the GLP requirements.

(c) *Agency guidelines.* EPA has published Test Guidelines that contain standards for conducting acceptable tests, guidance on the evaluation and reporting of data, definition of terms, and suggested study protocols. Copies of the Test Guidelines may be obtained by visiting the agency's website at *www.epa.gov/pesticides.*

(d) *Study protocols*—(1) *General.* Any appropriate protocol may be used to generate the data required by this part, provided that it meets the purpose of the test standards specified in the pesticide assessment guidelines, and provides data of suitable quality and completeness as typified by the protocols cited in the guidelines. Applicants should use the test procedure which is most suitable for evaluation of the particular ingredient, mixture, or product. Accordingly, failure to follow a suggested protocol will not invalidate a test if another appropriate methodology is used.

(2) *Organization for Economic Co-Operation and Development (OECD) protocols.* Tests conducted in accordance with the requirements and recommendations of the applicable OECD protocols can be used to develop data necessary to meet the requirements specified in this part. Applicants should note, however, that certain of the OECD recommended test standards, such as test duration and selection of test species, are less restrictive than those recommended by EPA. Therefore, when using OECD protocols, care should be taken to observe the test standards in a manner such that the data generated by the study will satisfy the requirements of this part.

(e) *Combining studies.* Certain toxicology studies may be combined to satisfy data requirements. For example, carcinogenicity studies in rats may be combined with the rat chronic toxicity study. Combining appropriate studies may be expected to reduce usage of test animals as well as reduce the cost of studies. EPA encourages this practice by including standards for acceptable combined tests in the Pesticide Assessment Guidelines. Registrants and applicants are encouraged to consider combining other tests when practical and likely to produce scientifically acceptable results. Registrants and applicants, however, must consult with the EPA before initiating combined studies.

§ 158.75 Requirements for additional data.

The data routinely required by this part may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties and effects of the pesticide.

§ 158.80 Use of other data.

(a) *Data developed in foreign countries.* With certain exceptions, laboratory and field study data developed outside the United States may be submitted in support of a pesticide registration. Data generated in a foreign country which the Agency will not consider include, but are not limited to, data from tests which involved field test sites or a test material, such as a native soil, plant, or animal, that is not characteristic of the United States. Applicants submitting foreign data must take steps to ensure that U.S. materials are used, or be prepared to supply data or information to demonstrate the lack of substantial or relevant differences between the selected material or test site and the U.S. material or test site. Once submitted, the Agency will determine whether or not the data meet the data requirements.

(b) *Data generated for other purposes.* Data developed for purposes other than satisfaction of FIFRA data requirements, such as monitoring studies, may also satisfy data requirements in this part. Consultation with the Agency should be arranged if applicants are unsure about suitability of such data.

Subpart B—How to Use Data Tables

§ 158.100 Pesticide use patterns.

(a) *General use patterns.* There are six broad use categories used in the data tables. The six broad categories include terrestrial outdoor uses, aquatic outdoor uses, greenhouse uses, forestry uses, residential outdoor uses, and indoor

uses of all types. The 6 broad use categories are further subdivided into 12 general use patterns which are the bases for data requirements established by use pattern. Within the data tables, general use patterns have been combined into single columns when the data requirements are the same for the combined uses. If there are no data requirements for a specific use, the column for that use is not included in the table. The 12 general use pattern groups used in the data table in this part are:

(1) Terrestrial food crop use.
(2) Terrestrial feed crop use.
(3) Terrestrial nonfood crop use.
(4) Aquatic food crop use.
(5) Aquatic nonfood use.
(6) Greenhouse food crop use.
(7) Greenhouse nonfood crop use.
(8) Forestry use.
(9) Residential outdoor use.
(10) Residential indoor use.
(11) Indoor food use.
(12) Indoor nonfood use.

(b) *Pesticide use site index*. The Pesticide Use Site Index is a comprehensive list of specific pesticide use sites. The index is alphabetized separately by site for all agricultural and all nonagricultural uses. The Pesticide Use Site Index associates each pesticide use site with one or more of the 12 general use patterns. It may be used in conjunction with the data tables to determine the applicability of data requirements to specific uses. The Pesticide Use Site Index, which will be updated periodically, is available from the Agency or may be obtained from the Agency's website at *http://www.epa.gov/pesticides*.

(c) Applicants unsure of the correct use pattern for their particular product should consult the Agency.

§ 158.110 Required and conditionally required data.

The tables in this part use the descriptors R (required), CR (conditionally required), and NR (not required) as a general indication of the applicability of a data requirement. In all cases, the test notes referred to in the table must be consulted to determine the actual applicability of the data requirement.

(a) EPA requires data designated as ''required''(R) for products with a given use pattern in order to evaluate the risks or benefits of a product having that use pattern under any conditions established by the test notes.

(b) Data designated as ''conditionally required'' (CR) for products with a given use pattern are required by EPA to evaluate the risks or benefits of a product having that use pattern if the product meets the conditions specified in the notes accompanying the requirement. The determination of whether the data must be submitted is based on the product's use pattern, physical or chemical properties, expected exposure of nontarget organisms, and/or results of previous testing (for example, tier testing). Applicants must evaluate each applicable test note for the conditions and criteria to be considered in determining whether conditionally required data must be submitted.

(c) Data not required for the Agency's assessment of the risks and benefits of a particular use pattern are designated ''not required'' (NR) in data tables.

§ 158.120 Determining data requirements.

As with current practice, the actual data and studies required may be modified on an individual basis to fully characterize the use and properties of specific pesticide products under review. While EPA is attempting to assist the applicant in this subpart, it is important to emphasize that it is the applicant's obligation under FIFRA to demonstrate that an individual product meets the standard under FIFRA and/or FFDCA. Accordingly, applicants are encouraged to consult with the Agency on the appropriate data requirements as set forth here as they relate to their specific product prior to and during the registration process.

(a) *Finding the appropriate data table*. (1) Pesticide data requirements for conventional chemical active ingredients and related substances are presented in subparts D, E, F, G, K, L, N, and O of this part in the form of a series of data tables, each addressing a particular scientific discipline or data topic. Data requirements for biochemical and microbial pest control agents are contained and are described separately within subparts U and V of this part, respectively.

(2) Key to table notations. R = required data; CR = conditionally required data; NR = Not required; MP = manufacturing-use product; EP = end-use product; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = pure active ingredient; PAIRA = pure active ingredient, radiolabeled; Choice = choice of several test substances depending on studies required.

(b) *Identifying required studies*. To determine the specific kinds of data needed to support the registration use of each pesticide product, the applicant may:

(1) Refer to the applicable subpart(s) of this part. These subparts describe the data requirements including data tables for each subject area.

(2) Select the general use pattern(s) that best cover the use pattern(s) specified on the pesticide product label as explained in § 158.100. All applicable use patterns must be included.

(3) Proceed down the appropriate general use pattern column in the table and note which tests are required (R), conditionally required (CR), or not required (NR). Required and conditionally required studies are described in § 158.110.

(4) Review the notes for each requirement to determine its applicability to the specific product proposed for registration.

(5)(i) Proceed down the Test substance columns and determine the appropriate test substance needed for that study. If the data are intended to support a manufacturing-use product, use the MP column. If the data are intended to support an end-use product, use the EP column.

(ii) The test substances columns specify which substance is to be used for testing. Applicants should note that the substance that must be used when performing the study may or may not be the product itself. For example, the data from a certain study may be required to support the registration of an end-use product, but the test substance column may state that the particular test shall be performed using the technical grade of the active ingredient(s) in the end-use product.

(iii) Manufacturing-use products (MP) and end-use products (EP) containing a single active ingredient and no intentionally added inert ingredients are considered identical in composition to each other, and to the technical grade of the active ingredient (TGAI) from which they were derived. Therefore, the data from a test conducted using any one of these as the test substance is also suitable to meet the requirement (if any) for the same test to be conducted using either of the other substances.

(6) Refer to the Pesticide Assessment Guideline reference number for each study located in the first column. See § 158.70(c) for information pertaining to the guidelines and how to obtain copies.

§ 158.130 Purposes of the registration data requirements.

(a) *General*. The data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.

(b) *Product chemistry*—(1) *Product composition*. Data on product composition are needed:

(i) To support the conclusions expressed in the statement of formula;

(ii) To compare to the composition of materials used in required testing under this part; and

(iii) To determine whether a product is ''identical or substantially similar''to another product, a determination that involves the comparison of product composition.

(2) *Nominal concentration and certified limits*. The nominal concentration of a product, defined as that concentration that is expected to be present in a product as a result of the production or formulation process, is used to gauge the acceptability of the certified limits, which define the outer limits of the range of the product's ingredients. The certified limits are used to enforce the composition of the product and to ensure the accuracy of hazard assessments.

(3) *Physical and chemical characteristics*. The physical and chemical characteristics of an active ingredient or product are used:

(i) To confirm or provide supportive information on the identity and composition of the product;

(ii) To assess the hazards of the ingredient or product; and

(iii) To trigger or evaluate certain other studies required by this part.

(c) *Product performance*. Requirements to develop data on product performance provide a mechanism to ensure that pesticide products will perform as intended and that unnecessary pesticide exposure to the environment will not occur as a result of the use of ineffective products. Specific performance standards are used to validate the efficacy data in the public health areas, including disinfectants used to control microorganisms infectious to man in any area of the inanimate environment and those pesticides used to control vertebrates (such as rodents, birds, bats and skunks) that may directly or indirectly transmit diseases to humans.

(d) *Toxicology-humans and domestic animals*. Data required to assess hazards to humans and domestic animals are derived from a variety of acute, subchronic and chronic toxicity tests, and tests to assess mutagenicity and pesticide metabolism.

(1) *Acute studies*. Determination of acute oral, dermal and inhalation toxicity is usually the initial step in the assessment and evaluation of the toxic characteristics of a pesticide. These data provide information on health hazards likely to arise soon after, and as a result of, short-term exposure. Data from acute studies serve as a basis for classification and precautionary labeling. For example, acute toxicity data are used to calculate farmworker reentry intervals and to develop precautionary label statements pertaining to protective clothing requirements for applicators. They also provide information used in establishing the appropriate dose levels in subchronic and other studies; provide initial information on the mode of toxic action(s) of a substance; and determine the need for child resistant packaging. Information derived from primary eye and primary dermal irritation studies serves to identify possible hazards from exposure of the eyes, associated mucous membranes and skin.

(2) *Subchronic studies*. Subchronic tests provide information on health hazards that may arise from repeated exposures over a limited period of time. They provide information on target organs and accumulation potential. The resulting data are also useful in selecting dose levels for chronic studies and for establishing safety criteria for human exposure. These tests are not capable of detecting those effects that have a long latency period for expression (*e.g.*, carcinogenicity).

(3) *Chronic studies*. Chronic toxicity studies (usually conducted by feeding the test substance to the test species) are intended to determine the effects of a substance in a mammalian species following prolonged and repeated exposure. Under the conditions of this test, effects which have a long latency period or are cumulative should be detected. The purpose of long-term carcinogenicity studies is to observe test animals over most of their life span for the development of neoplastic lesions during or after exposure to various doses of a test substance by an appropriate route of administration.

(4) *Developmental toxicity and reproduction studies*. The developmental toxicity study is designed to determine the potential of the test substance to induce structural and/or other abnormalities to the fetus as the result of exposure of the mother during pregnancy. Two-generation reproduction testing is designed to provide information concerning the general effects of a test substance on gonadal function, estrus cycles, mating behavior, conception, parturition, lactation, weaning, and the growth and development of the offspring. The study may also provide information about the effects of the test substance on neonatal morbidity, mortality, and preliminary data on prenatal developmental toxicity and serve as a guide for subsequent tests.

(5) *Mutagenicity studies*. For each test substance a battery of tests is required to assess the potential to affect the mammalian cell's genetic components. The objectives underlying the selection of a battery of tests for mutagenicity assessment are:

(i) To detect, with sensitive assay methods, the capacity of a chemical to alter genetic material in cells.

(ii) To determine the relevance of these mutagenic changes to mammals.

(iii) When mutagenic potential is demonstrated, to incorporate these findings in the assessment of heritable effects, carcinogenicity, and, possibly, other health effects.

(6) *Metabolism studies*. Data from studies on the absorption, distribution, metabolism, and excretion of a pesticide aid in the valuation of test results from other toxicity studies and in the extrapolation of data from animals to man. The main purpose of metabolism studies is to produce data which increases the Agency's understanding of the behavior of the chemical when considering the human exposure anticipated from intended uses of the pesticide.

(e) *Hazards to nontarget organisms*—(1) *General*. The information required to assess hazards to nontarget organisms is derived from tests to determine pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates and plants. These tests include short-term acute, subacute, reproduction, simulated field, and full field studies arranged in a hierarchical or tier system which progresses from the basic laboratory tests to the applied field tests. The results of each tier of testing must be evaluated to determine the potential of the pesticide to cause adverse effects, and to determine whether further testing is required. A purpose common to all data requirements is to provide data which determine the need for (and appropriate wording for) precautionary label statements to minimize the potential adverse effects to nontarget organisms.

(2) *Short-term studies*. The short-term acute and subchronic laboratory studies provide basic toxicity information which serves as a starting point for the hazard assessment. These data are used: To establish acute toxicity levels of the active ingredient to the test organisms; to compare toxicity information with measured or estimated pesticide residues in the environment in order to assess potential impacts on fish, wildlife and other nontarget organisms; and to indicate whether further laboratory and/or field studies are needed.

(3) *Long-term and field studies*. Additional studies (*i.e.*, avian, fish, and

invertebrate reproduction, life cycle studies and plant field studies) may be required when basic data and environmental conditions suggest possible problems. Data from these studies are used to: Estimate the potential for chronic effects, taking into account the measured or estimated residues in the environment; and to determine if additional field or laboratory data are necessary to further evaluate hazards. Simulated field and/or field data are used to examine acute and chronic adverse effects on captive or monitored fish and wildlife populations under natural or near-natural environments. Such studies are required only when predictions as to possible adverse effects in less extensive studies cannot be made, or when the potential for adverse effects is high.

(f) *Applicator and post-application exposure.* Data are used to evaluate exposures to persons in occupational and non-occupational settings, including agricultural, residential, commercial, institutional and recreational sites. Data include oral, dermal and inhalation exposure data, post-application residue data, post-application monitoring data, use information, and human activity information. These data, together with toxicology data, are used to determine whether application or post-application risks are of concern, and, where appropriate, to develop post-application restrictions such as reentry restrictions.

(g) *Pesticide spray drift evaluation.* Data required to evaluate pesticide spray drift are derived from studies of droplet size spectrum and spray drift field evaluations. These data contribute to the development of the overall exposure estimate and, along with data on toxicity for humans, fish and wildlife, or plants, are used to assess the potential hazard of pesticides to these organisms. A purpose common to all these tests is to provide data which will be used to determine the need for (and appropriate wording for) precautionary labeling to minimize the potential adverse effect to nontarget organisms.

(h) *Environmental fate*—(1) *General.* The data generated by environmental fate studies are used to: Assess the toxicity to man through exposure of humans to pesticide residues remaining after application, either upon reentering treated areas or from consuming inadvertantly-contaminated food; assess the presence of widely distributed and persistent pesticides in the environment which may result in loss of usable land, surface water, ground water, and wildlife resources; and, assess the potential environmental exposure of other nontarget organisms, such as fish and wildlife, to pesticides. Another specific purpose of the environmental fate data requirements is to help applicants and the Agency estimate expected environmental concentrations of pesticides in specific habitats where threatened or endangered species or other wildlife populations at risk are found.

(2) *Degradation studies.* The data from hydrolysis and photolysis studies are used to determine the rate of pesticide degradation and to identify pesticides that may adversely affect nontarget organisms.

(3) *Metabolism studies.* Data generated from aerobic and anaerobic metabolism studies are used to determine the nature and availability of pesticides to rotational crops and to aid in the evaluation of the persistence of a pesticide.

(4) *Mobility studies.* These data requirements pertain to leaching, adsorption/desorption, and volatility of pesticides. They provide information on the mode of transport and eventual destination of the pesticide in the environment. This information is used to assess potential environmental hazards related to: Contamination of human and animal food; loss of usable land and water resources to man through contamination of water (including ground water); and habitat loss of wildlife resulting from pesticide residue movement or transport in the environment.

(5) *Dissipation studies.* The data generated from dissipation studies are used to assess potential environmental hazards (under actual field use conditions) related to: Reentry into treated areas; hazards from residues in rotational crops and other food sources; and the loss of land as well as surface and ground water resources.

(i) *Residue chemistry.* (1) Residue chemistry data are used by the Agency to estimate the exposure of the general population to pesticide residues in food and for setting and enforcing tolerances for pesticide residues in food or feed.

(2) Information on the chemical identity and composition of the pesticide product, the amounts, frequency and time of the pesticide application, and results of tests on the amount of residues remaining on or in the treated food or feed, are needed to support a finding as to the magnitude and identity of residues which result in food or animal feed as a consequence of a proposed pesticide usage.

(3) Residue chemistry data are also needed to support the adequacy of one or more methods for the enforcement of the tolerance, and to support practicable methods for removing residues that exceed any proposed tolerance.

(4) *Accumulation studies.* Accumulation studies indicate pesticide residue levels in food supplies that originate from wild sources or from rotational crops. Rotational crop studies are necessary to establish realistic crop rotation restrictions and to determine if tolerances may be needed for residues on rotational crops. Data from irrigated crop studies are used to determine the amount of pesticide residues that could be taken up by representative crops irrigated with water containing pesticide residues. These studies allow the Agency to establish label restrictions regarding application of pesticides on sites where the residues can be taken up by irrigated crops. These data also provide information that aids the Agency in establishing any corresponding tolerances that would be needed for residues on such crops. Data from pesticide accumulation studies in fish are used to establish label restrictions to prevent applications in certain sites so that there will be minimal residues entering edible fish or shellfish. These residue data are also used to determine if a tolerance or action level is needed for residues in aquatic animals eaten by humans.

Subpart C—Experimental Use Permits

§ 158.200 Experimental use permit data requirements tables.

Sections 158.200 through 158.270 describe how to use these tables to determine the experimental use permit data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed at the end of each table. Refer to 40 CFR part 172 for further information on experimental use permits.

§ 158.210 Experimental use permit data requirements for product chemistry.

All product chemistry data, as described in § 158.310, must be submitted to support a request for an experimental use permit.

§ 158.220 Experimental use permit data requirements for product performance.

All product performance data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop

and aquatic nonfood crop. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for forestry and residential outdoor uses.

(b) *Key*. CR=Conditionally required; NR=Not required; R=Required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product.

(c) *Table*. The following table shows the experimental use data requirements for product performance. The test notes are shown in paragraph (d) of this section.

TABLE—DATA REQUIREMENTS FOR PRODUCT PERFORMANCE

Guideline No.	Data Requirement	Use Pattern									Test substance to support		Test Note No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Residential Outdoors	Indoor	MP	EP	
		Food Crop	Nonfood Crop	Food Crop	Nonfood Crop	Food Crop	Nonfood Crop						
Efficacy of antimicrobial agents													
91–8	Products for treating water systems	NR	NR	CR	NR	NR	NR	NR	NR	NR	NR	EP	1
Efficacy of fungicides and nematicides													
93–16	Products for control of organisms producing mycotoxins	CR	NR	CR	NR	CR	NR	NR	NR	NR	NR	EP	1
Efficacy of vertebrate control agents													
96–5	Avian toxicants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
96–6	Avian repellents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96–7	Avian frightening agents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96–9	Bat toxicants and repellents	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	EP	1
96–10	Commensal rodenticides	R	R	NR	NR	NR	NR	NR	R	R	TEP	EP	1
96–12	Rodenticides on farm and rangelands	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
95–13	Rodent fumigants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95–16	Rodent reproductive inhibitors	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95–17	Mammalian predacides	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1

(d) *Test notes*. The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. The Agency has waived the requirement to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

2. [Reserved]

§ 158.230 Experimental use permit data requirements for toxicology.

All toxicology data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use, aquatic nonfood crop use, aquatic nonfood outdoor use, greenhouse nonfood crop use, forestry use, residential outdoor use, indoor nonfood use, and indoor residential use.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; EP=End-use product; MP=Manufacturing-use product; PAIRA=Pure active ingredient radio-labeled; TGAI=Technical grade of the active ingredient.

(c) *Table.* The following table shows the experimental use data requirements for toxicology. The test notes are shown in paragraph (d) of this section.

TABLE—TOXICOLOGY DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	MP and TGAI	TGAI, EP	1
870.1200	Acute dermal toxicity	R	R	MP and TGAI	TGAI, EP	1, 2
870.1300	Acute inhalation toxicity - rat	R	R	MP and TGAI	TGAI and EP	3
870.2400	Primary eye irritation - rabbit	R	R	MP	TGAI and EP	2
870.2500	Primary dermal irritation	R	R	MP	TGAI and EP	1, 2
870.2600	Dermal sensitization	R	R	MP	TGAI and EP	2, 4
870.6100	Delayed neurotoxicity (acute) - hen	CR	CR	TGAI	TGAI	5
Subchronic Testing						
870.3100	90–day Oral - rodent	R	NR	TGAI	TGAI	--
870.3150	90–day Oral - non-rodent	R	NR	TGAI	TGAI	--
Chronic Testing						
870.4100	Chronic oral - rodent	R	NR	TGAI	TGAI	6
Developmental Toxicity and Reproduction						
870.3700	Prenatal Developmental toxicity - rat and rabbit, preferred	R	NR	TGAI	TGAI	7, 8
870.3800	Reproduction	R	NR	TGAI	TGAI	6
Mutagenicity Testing						
870.5100	Bacterial reverse mutation assay	R	NR	TGAI	TGAI	9
870.5300 870.5375	*In vitro* mammalian cell assay	R	NR	TGAI	TGAI	9, 10
870.5385 870.5395	*In vivo* cytogenetics	R	NR	TGAI	TGAI	9, 11

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. Not required if test material is a gas or a highly volatile liquid.

2. Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

3. Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).

4. Required if repeated dermal exposure is likely to occur under conditions of use.

5. Required if the test material is an organophosphorus substance, which includes uncharged organophosphorus esters, thioesters, or anhydrides of organophosphoric, organophosphonic, or organophosphoramidic acids, or of related phosphorothioic, phosponothioic, or phosphorothioamidic acids, or is structurally related to other substances that may cause the delayed neurotoxicity sometimes seen in this class of chemicals.

6. These studies are seldom required to support EUPs. They may be required if the dietary exposure for these EUPs occupies a large part, e.g., greater than 50%, of the reference dose.

7. The oral route, by oral intubation, is preferred unless the chemical or physical properties of the test substance or the pattern of exposure suggests a more appropriate route of exposure.

8. May be combined with the 2–generation reproduction study in rodents by utilizing a second mating of the parental animals in either generation.

9. At a minimum, an initial battery of mutagenicity tests with possible confirmatory testing is required. Other relevant mutagenicity tests that may have been performed, plus a complete reference list must also be submitted.

10. Choice of assay using either:

i. Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression or detection;

ii. Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgprt) gene locus, accompanied by an appropriate *in vitro* test for clastogenicity; or

iii. CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xprt) gene locus.

11. The micronucleus rodent bone marrow assay is preferred; however, rodent bone marrow assays using metaphase analysis (aberrations) are acceptable.

§ 158.240 Experimental use permit data requirements for ecological effects.

All data for terrestrial nontarget organisms and aquatic nontarget organisms as described in § 158.243 must be submitted to support a request for an experimental use permit. No data for nontarget plant protection must be submitted to support a request for an experimental use permit.

§ 158.243 Experimental use permit data requirements for terrestrial and aquatic nontarget organisms.

All terrestrial and aquatic nontarget organism data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for the general use patterns of forestry and residential outdoor use.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; commas between the test substances (e.g. TGAI, TEP) indicate that data may be required on the TGAI or TEP depending on the conditions set forth in the test note.

(c) *Table.* The following table shows the experimental use data requirements for terrestrial and aquatic nontarget organisms. The test notes are shown in paragraph (d) of this section.

TABLE—TERRESTRIAL AND AQUATIC NONTARGET ORGANISMS DATA REQUIREMENTS

Guideline No.	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
Avian and Mammalian Testing									
850.2100	Avian oral toxicity	R	R	R	R	CR	CR	TGAI	1, 2, 3
850.2200	Avian dietary toxicity	R	R	R	R	NR	NR	TGAI	1, 4
Aquatic Organisms Testing									
850.1075	Freshwater fish toxicity	R	R	R	NR	NR	NR	TGAI, TEP	1, 2, 5, 6, 11
850.1010	Acute toxicity freshwater invertebrates	R	R	R	NR	NR	NR	TGAI, TEP	1, 2, 6, 7, 11
850.1300	Aquatic invertebrate life cycle (freshwater)	NR	R	R	NR	NR	NR	TGAI	1, 7, 8
850.1400	Fish early-life stage (freshwater)	NR	R	R	NR	NR	NR	TGAI	1, 8, 9
Accumulation Study									
850.1730	Fish	CR	CR	CR	NR	NR	NR	TGAI or PAIRA	10
Insect Pollinator Testing									
850.3020	Honeybee acute contact toxicity	R	R	R	NR	NR	NR	TGAI	1

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. Data using the TGAI are required to support all outdoor end-use product uses including, but not limited to, turf. Data are generally not required to support end-use products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material.

2. For greenhouse and indoor end-use products, data using the TGAI are required to support manufacturing-use products to be reformulated into these same end-use products or to support end-use products when there is no registered manufacturing-

use product. Avian acute oral data are not required for liquid formulations for greenhouse and indoor uses. The study is not required if there is no potential for environmental exposure.

3. Data are required on one passerine species and either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. Data are preferred on waterfowl or upland game bird species for indoor and greenhouse uses.

4. Data are required on waterfowl and upland game bird species.

5. Data are required on one coldwater fish and one warmwater fish for terrestrial, aquatic, forestry, and residential outdoor uses. For indoor and greenhouse uses, testing with only one of either fish species is required.

6. EP or TEP testing is required for any product which meets any of the following conditions:

i. The end-use pesticide will be introduced directly into an aquatic environment (e.g., aquatic herbicides and mosquito larvicides) when used as directed.

ii. The maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment is ≥ one-half the LC_{50} or EC_{50} of the TGAI when the EP is used as directed.

iii. An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

7. Data are required on one freshwater aquatic invertebrate species.

8. Data are generally not required for outdoor residential uses, other than turf, unless data indicate that pesticide residues from the proposed use(s) can potentially enter waterways.

9. Data are required on one freshwater fish species. If the test species is different from the two species used for the freshwater fish acute toxicity tests, a 96 hour LC_{50} on that species must also be provided.

10. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are < 1,000; or

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is < 5 days at pH 5, 7 and 9.

11. The freshwater fish test species for the TEP testing is the most sensitive of the species tested with the TGAI. A freshwater invertebrate must also be tested with the EP or TEP using the same species tested with the TGAI.

§ 158.250 Experimental use permit data requirements for human exposure.

No data for applicator exposure and post-application exposure must be submitted to support a request for an experimental use permit.

§ 158.260 Experimental use permit data requirements for environmental fate.

All environmental fate data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood. The aquatic use pattern includes the general use patterns of aquatic food crop, aquatic nonfood residential, and aquatic nonfood outdoors. The greenhouse use pattern includes both food and nonfood uses. The indoor use pattern includes food, nonfood, and residential indoor uses.

(2) Data are also required for the general use patterns of forestry use and residential outdoor use.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; PAIRA=Pure active ingredient radiolabeled; TGAI=Technical grade of the active ingredient.

(c) *Table.* The following table shows the experimental use data requirements for environmental fate. The test notes are shown in paragraph (d) of this section.

TABLE—ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline No.	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Greenhouse	Indoors	Forestry	Residential Outdoors		
Degradation Study - Laboratory									
835.2120	Hydrolysis	R	R	R	NR	R	R	TGAI or PAIRA	1
Metabolism Studies - Laboratory									
835.4100	Aerobic soil	R	CR	NR	NR	R	NR	TGAI or PAIRA	2
835.4300	Aerobic aquatic	NR	R	NR	NR	NR	NR	TGAI or PAIRA	--
Mobility Study									
835.1230 835.1240	Leaching and adsorption/desorption	R	NR	NR	NR	R	NR	TGAI or PAIRA	3

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. Study is required for indoor uses in cases where environmental exposure is likely to occur. Such sites include, but are not limited to, agricultural premises, in or around farm buildings, barnyards, and beehives.

2. Required for aquatic uses for aquatic sites that are intermittently dry. Such sites include, but are not limited to cranberry bogs and rice paddies.

3. Adsorption and desorption using a batch equilibrium method is preferred. However, in some cases, for example, where the pesticide degrades rapidly, soil column leaching with unaged or aged columns may be more appropriate to fully characterize the potential mobility of the parent compound and major transformation products.

§ 158.270 Experimental use permit data requirements for residue chemistry.

All residue chemistry data, as described in § 158.1410, are required for an experimental use permit for which a temporary tolerance under FFDCA

section 408(r) is sought. Residue chemistry data are not required for an experimental use permit issued on a crop-destruct basis.

§§ 158.280 - 158.290 [Reserved]

Subpart D—Product Chemistry

§ 158.300 Definitions.

The following terms are defined for the purposes of this subpart:

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, defoliant, or nitrogen stabilizer, within the meaning of FIFRA sec. 2(b).

End-use product means a pesticide product whose labeling:

(1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating or regulating growth of plants, or as a nitrogen stabilizer, and

(2) does not state that the product may be used to manufacture or formulate other pesticide products.

Formulation means:

(1) The process of mixing, blending, or dilution of one or more active ingredients with one or more other active or inert ingredients, without an intended chemical reaction, to obtain a manufacturing-use product or an end-use product, or

(2) The repackaging of any registered product.

Impurity means any substance (or group of structurally similar substances if specified by the Agency), in a pesticide product other than an active ingredient or an inert ingredient, including unreacted starting materials, side reaction products, contaminants, and degradation products.

Impurity associated with an active ingredient means:

(1) Any impurity present in the technical grade of active ingredient; and

(2) Any impurity which forms in the pesticide product through reactions between the active ingredient and any other component of the product or packaging of the product.

Inert ingredient means any substance (or group of structurally similar substances if designated by the Agency), other than the active ingredient, which is intentionally included in a pesticide product.

Integrated system means a process for producing a pesticide product that:

(1) Contains any active ingredient derived from a source that is not an EPA-registered product; or

(2) Contains any active ingredient that was produced or acquired in a manner that does not permit its inspection by the Agency under FIFRA sec. 9(a) prior to its use in the process.

Manufacturing-use product means any pesticide product other than an end-use product. A product may consist of the technical grade of active ingredient only, or may contain inert ingredients, such as stabilizers or solvents.

Nominal concentration means the amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight.

Starting material means a substance used to synthesize or purify a technical grade of active ingredient (or the practical equivalent of the technical grade ingredient if the technical grade cannot be isolated) by chemical reaction.

Technical grade of active ingredient means a material containing an active ingredient:

(1) Which contains no inert ingredient, other than one used for purification of the active ingredient; and

(2) Which is produced on a commercial or pilot plant production scale (whether or not it is ever held for sale).

§ 158.310 Product chemistry data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product chemistry data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (f) of the section.

(b) *Use patterns.* Product chemistry data are required for all pesticide products and are not use-specific.

(c) *Test substance.* Data requirements that list only the manufacturing-use product as the test substance apply to products containing solely the technical grade of the active ingredient and manufacturing-use products to which other ingredients have been intentionally added.

(d) *Key.* R=Required; CR=Conditionally required; MP=Manufacturing-use product; NR=Not required; EP=End-use product; TGAI=Technical grade of the active ingredient; PAI=Pure active ingredient.

(e) *Table.* The following table shows the data requirements for product chemistry. The table notes are shown in paragraph (f) of this section.

PRODUCT CHEMISTRY DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern	Test substance to support		Test Note No.
		All	MP	EP	
Product Identity and Composition					
830.1550	Product identity and composition	R	MP	EP	1
830.1600	Description of materials used to produce the product	R	MP	EP	2
830.1620	Description of production process	R	MP	EP	3
830.1650	Description of formulation process	R	MP	EP	4
830.1670	Discussion of formulation of impurities	R	MP, and possibly TGAI	EP, and possibly TGAI	5
830.1700	Preliminary analysis	CR	MP, and possibly TGAI	EP, and possibly TGAI	6, 9, 10

PRODUCT CHEMISTRY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern	Test substance to support		Test Note No.
		All	MP	EP	
830.1750	Certified limits	R	MP	EP	7
830.1800	Enforcement analytical method	R	MP	EP	8
830.1900	Submittal of samples	CR	MP, PAI and TGAI	EP, PAI, TGAI	9, 11
Physical and Chemical Properties.					
830.6302	Color	R	MP and TGAI	EP	9
830.6303	Physical state	R	MP and TGAI	EP and TGAI	9
830.6304	Odor	R	MP and TGAI	EP	9
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	R	MP and TGAI	EP	9, 12, 26
830.6314	Oxidation/reduction: chemical incompatibility	CR	MP	EP	13
830.6315	Flammability	CR	MP	EP	14
830.6316	Explodability	CR	MP	EP	15
830.6317	Storage stability	R	MP	EP	
830.6319	Miscibility	CR	MP	EP	16
830.6320	Corrosion characteristics	R	MP	EP	
830.6321	Dielectric breakdown voltage	CR	NR	EP	17
830.7000	pH	CR	MP and TGAI	EP and TGAI	9, 18
830.7050	UV/visible light absorption	R	TGAI or PAI	NR	--
830.7100	Viscosity	CR	MP	EP	19
830.7200	Melting point/melting range	R	TGAI or PAI	TGAI or PAI	9, 20
830.7220	Boiling point/boiling range	R	TGAI or PAI	TGAI or PA	9, 21
830.7300	Density/relative density/bulk density	R	MP and TGAI	EP and TGAI	9
830.7370	Dissociation constants in water	R	TGAI or PAI	TGAI or PAI	9, 22
830.7520	Particle size, fiber length, and diameter distribution	CR	TGAI or PAI	EP	23
830.7550 830.7560 830.7570	Partition coefficient (n-octanol/water)	R	TGAI or PAI	TGAI or PAI	24
830.7840 830.7860	Water solubility	R	TGAI or PAI	TGAI or PAI	9
830.7950	Vapor pressure	R	TGAI or PAI	TGAI or PAI	9, 25

(f) *Test notes.* The following test notes are applicable to the product chemistry data requirements in the table to paragraph (e) of this section:

1. Data must be provided in accordance with § 158.320.

2. Data must be provided in accordance with § 158.325.

3. Data must be provided in accordance with § 158.330.

4. Data must be provided in accordance with § 158.335.

5. Data must be provided in accordance with § 158.340.

6. Data must be provided in accordance with § 158.345.

7. Data must be provided in accordance with § 158.350.

8. Data must be provided in accordance with § 158.355.

9. If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI.

10. Data are required if the product is produced by an integrated system.

11. Basic manufacturers are required to provide the Agency with a sample of each TGAI used to formulate a product produced by an integrated system when the new TGAI is first used as a formulating ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end-use products produced by an integrated system must be submitted on a case-by-case basis.

12. Data on the stability to metals and metal ions are required only if the TGAI is

expected to come into contact with either material.

13. Required when the product contains an oxidizing or reducing agent.

14. Required when the product contains combustible liquids.

15. Required when the product is potentially explosive.

16. Required when the product is an emulsifiable liquid and is to be diluted with petroleum solvent.

17. Required when the EP is a liquid and is to be used around electrical equipment.

18. Required when the test substance is soluble or dispersible in water.

19. Required when the product is a liquid.

20. Required when the TGAI is solid at room temperature.

21. Required when the TGAI is liquid at room temperature.

22. Required when the test substance contains an acid or base functionality (organic or inorganic) or an alcoholic functionality (organic).

23. Required for water insoluble test substances ($>10^{-6}$ g/l) and fibrous test substances with diameter of ≥0.1 μm.

24. Required if technical chemical is organic and non-polar.

25. Not required for salts.

26. Data on stability of the MP and TGAI to storage at normal temperatures are required. Data on the stability of the TGAI to high temperatures are required if the TGAI is expected to be subjected to temperatures >50° C (122° F) during production or storage.

§ 158.320 Product identity and composition.

Information on the composition of the pesticide product must be furnished. The information required by paragraphs (a), (b), and (f) of this section must be provided for each product. In addition, if the product is produced by an integrated system, the information on impurities required by paragraphs (c) and (d) of this section must be provided.

(a) *Active ingredient.* The following information is required for each active ingredient in the product:

(1) If the source of any active ingredient in the product is an EPA-registered product:

(i) The chemical and common name (if any) of the active ingredient, as listed on the source product.

(ii) The nominal concentration of the active ingredient in the product, based upon the nominal concentration of active ingredient in the source product.

(iii) Upper and lower certified limits of the active ingredient in the product, in accordance with § 158.350.

(2) If the source of any active ingredient in the product is not an EPA-registered product:

(i) The chemical name according to Chemical Abstracts Society (CAS) nomenclature, the CAS Registry Number, and any common names.

(ii) The molecular, structural, and empirical formulae and the molecular weight or weight range.

(iii) The nominal concentration.

(iv) Upper and lower certified limits of the active ingredient in accordance with § 158.350.

(v) The purpose of the ingredient in the formulation.

(b) *Inert ingredients.* The following information is required for each inert ingredient (if any) in the product:

(1) The chemical name of the ingredient according to Chemical Abstracts Society nomenclature, the CAS Registry Number, and any common names (if known). If the chemical identity or chemical composition of an ingredient is not known to the applicant because it is proprietary or trade secret information, the applicant must ensure that the supplier or producer of the ingredient submits to the Agency (or has on file with the Agency) information on the identity or chemical composition of the ingredient. Generally, it is not required that an applicant know the identity of each ingredient in a mixture that he uses in his product. However, in certain circumstances, the Agency may require that the applicant know the identity of a specific ingredient in such a mixture. If the Agency requires specific knowledge of an ingredient, it will notify the applicant in writing.

(2) The nominal concentration.

(3) Upper and lower certified limits in accordance with § 158.350.

(4) The purpose of the ingredient in the formulation.

(c) *Impurities of toxicological significance associated with the active ingredient.* For each impurity associated with the active ingredient that is determined by EPA to be toxicologically significant, the following information is required:

(1) Identification of the ingredient as an impurity.

(2) The chemical name of the impurity.

(3) The nominal concentration of the impurity in the product.

(4) A certified upper limit, in accordance with § 158.350.

(d) *Other impurities associated with the active ingredient.* For each other impurity associated with an active ingredient that was found to be present in any sample at a level ≥0.1 percent by weight of the technical grade active ingredient the following information is required:

(1) Identification of the ingredient as an impurity.

(2) The chemical name of the impurity.

(3) The nominal concentration of the impurity in the final product.

(e) *Impurities associated with an inert ingredient.* [Reserved]

(f) *Ingredients that cannot be characterized.* If the identity of any ingredient or impurity cannot be specified as a discrete chemical substance (such as mixtures that cannot be characterized or isomer mixtures), the applicant must provide sufficient information to enable EPA to identify its source and qualitative composition.

§ 158.325 Description of materials used to produce the product.

The following information must be submitted on the materials used to produce the product:

(a) *Products not produced by an integrated system.* (1) For each active ingredient that is derived from an EPA-registered product:

(i) The name of the EPA-registered product.

(ii) The EPA registration number of that product.

(2) For each inert ingredient:

(i) Each brand name, trade name, common name, or other commercial designation of the ingredient.

(ii) All information that the applicant knows (or that is reasonably available to him) concerning the composition (and, if requested by the Agency, chemical and physical properties) of the ingredient, including a copy of technical specifications, data sheets, or other documents describing the ingredient.

(iii) If requested by the Agency, the name and address of the producer of the ingredient or, if that information is not known to the applicant, the name and address of the supplier of the ingredient.

(b) *Products produced by an integrated system.* (1) The information required by paragraph (a)(1) of this section concerning each active ingredient that is derived from an EPA-registered product (if any).

(2) The following information concerning each active ingredient that is not derived from an EPA-registered product:

(i) The name and address of the producer of the ingredient (if different from the applicant).

(ii) Information about each starting material used to produce the active ingredient, as follows:

(A) Each brand name, trade name, or other commercial designation of the starting material.

(B) The name and address of the person who produces the starting material or, if that information is not known to the applicant, the name and address of each person who supplies the starting material.

(C) All information that the applicant knows (or that is reasonably available to

him), concerning the composition (and if requested by the Agency, chemical or physical properties) of the starting material, including a copy of all technical specifications, data sheets, or other documents describing it.

(3) The information required by paragraph (a)(2) of this section concerning each inert ingredient.

(c) *Additional information.* On a case-by-case basis, the Agency may require additional information on substances used in the production of the product.

§ 158.330 Description of production process.

If the product is produced by an integrated system, the applicant must submit information on the production (reaction) processes used to produce the active ingredients in the product. The applicant must also submit information about the formulation process, in accordance with § 158.335.

(a) Information must be submitted for the current production process for each active ingredient that is not derived from an EPA-registered product. If the production process is not continuous (a single reaction process from starting materials to active ingredient), but is accomplished in stages or by different producers, the information must be provided for each such production process.

(b) The following information must be provided for each process resulting in a separately isolated substance:

(1) The name and address of the producer who uses the process, if not the same as the applicant.

(2) A general characterization of the process (*e.g.*, whether it is a batch or continuous process).

(3) A flow chart of the chemical equations of each intended reaction occurring at each step of the process, and of the duration of each step and of the entire process.

(4) The identity of the materials used to produce the product, their relative amounts, and the order in which they are added.

(5) A description of the equipment used that may influence the composition of the substance produced.

(6) A description of the conditions (*e.g.*, temperature, pressure, pH, humidity) that are controlled during each step of the process to affect the composition of the substance produced, and the limits that are maintained.

(7) A description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced).

(8) A description of the procedures used to assure consistent composition of the substance produced, *e.g.*, calibration of equipment, sampling regimens, analytical methods, and other quality control methods.

§ 158.335 Description of formulation process.

The applicant must provide information on the formulation process of the product (unless the product consists solely of a technical grade of active ingredient) as required by the following sections:

(a) Section 158.330(b)(2), pertaining to characterization of the process.

(b) Section 158.330(b)(4), pertaining to ingredients used in the process.

(c) Section 158.330(b)(5), pertaining to process equipment.

(d) Section 158.330(b)(6), pertaining to the conditions of the process.

(e) Section 158.330(b)(8), pertaining to quality control measures.

§ 158.340 Discussion of formation of impurities.

The applicant must provide a discussion of the impurities that may be present in the product, and why they may be present. The discussion should be based on established chemical theory and on what the applicant knows about the starting materials, technical grade of active ingredient, inert ingredients, and production or formulation process. If the applicant has reason to believe that an impurity that EPA would consider toxicologically significant may be present, the discussion must include an expanded discussion of the possible formation of the impurity and the amounts at which it might be present. The impurities which must also be discussed are the following, as applicable:

(a) *Technical grade active ingredients and products produced by an integrated system.* (1) Each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the applicant.

(2) Each other impurity which the registrant or applicant has reason to believe may be present in his product at any time before use at a level ≥0.1 percent (1,000 ppm) by weight of the technical grade of the active ingredient, based on what he knows about the following:

(i) The composition (or composition range) of each starting material used to produce his product.

(ii) The impurities which the applicant knows are present (or believes are likely to be present) in the starting materials, and the known or presumed level (or range of levels) of these impurities.

(iii) The intended reactions and side reactions which may occur in the production of the product, and the relative amounts of byproduct impurities produced by such reactions.

(iv) The possible degradation of the ingredients in the product after its production but prior to its use.

(v) Post-production reactions between the ingredients in the product.

(vi) The possible migration of components of packaging materials into the pesticide.

(vii) The possible carryover of contaminants from use of production equipment previously used to produce other products or substances.

(viii) The process control, purification and quality control measures used to produce the product.

(b) *Products not produced by an integrated system.* Each impurity associated with the active ingredient which the applicant has reason to believe may be present in the product at any time before use at a level ≥0.1 percent (1,000 ppm) by weight of the product based on what he knows about the following:

(1) The possible carryover of impurities present in any registered product which serves as the source of any of the product's active ingredients. The identity and level of impurities in the registered source need not be discussed or quantified unless known to the formulator.

(2) The possible carryover of impurities present in the inert ingredients in the product.

(3) Possible reactions occurring during the formulation of the product between any of its active ingredients, between the active ingredients and inert ingredients, or between the active ingredient and the production equipment.

(4) Post-production reactions between any of the product's active ingredients and any other component of the product or its packaging.

(5) Possible migration of packaging materials into the product.

(6) Possible contaminants resulting from earlier use of equipment to produce other products.

(c) *Expanded discussion.* On a case-by-case basis, the Agency may require an expanded discussion of information on impurities:

(1) From other possible chemical reactions.

(2) Involving other ingredients.

(3) At additional points in the production or formulation process.

§ 158.345 Preliminary analysis.

(a) If the product is produced by an integrated system, the applicant must

provide a preliminary analysis of each technical grade of active ingredient contained in the product to identify all impurities present at 0. 1 percent or greater of the technical grade of the active ingredient. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substances are intended.

(b) Based on the preliminary analysis, a statement of the composition of the technical grade of the active ingredient must be provided. If the technical grade of the active ingredient cannot be isolated, a statement of the composition of the practical equivalent of the technical grade of the active ingredient must be submitted.

§ 158.350 Certified limits.

The applicant must propose certified limits for the ingredients in the product. Certified limits become legally binding limits upon approval of the application. Certified limits will apply to the product from the date of production to date of use. If the product label bears a statement prohibiting use after a certain date, the certified limits will apply only until that date.

(a) *Ingredients for which certified limits are required.* Certified limits are required on the following ingredients of a pesticide product:

(1) An upper and lower limit for each active ingredient.

(2) An upper and lower limit for each inert ingredient.

(3) If the product is a technical grade of active ingredient or is produced by an integrated system, an upper limit for each impurity of toxicological significance associated with the active ingredient and found to be present in any sample of the product.

(4) On a case-by-case basis, certified limits for other ingredients or impurities as specified by EPA.

(b) *EPA determination of standard certified limits for active and inert ingredients.* (1) Unless the applicant proposes different limits as provided in paragraph (c) of this section, the upper and lower certified limits for active and inert ingredients will be determined by EPA. EPA will calculate the certified limits on the basis of the nominal concentration of the ingredient in the product, according to the table in paragraph (b)(2) of this section.

(2) Table of standard certified limits.

STANDARD CERTIFIED LIMITS

If the nominal concentration (N) for the ingredient and percentage by weight for the ingredient is:	The certified limits for that ingredient will be as follows:	
	Upper Limit	Lower Limit
N≤1.0%	N + 10%N	N - 10%N
1.0% ≤N ≤20.0%	N + 5%N	N - 5%N
20.0%≤N≤100.0%	N + 3%N	N - 3%N

(c) *Applicant proposed limits.* (1) The applicant may propose a certified limit for an active or inert ingredient that differs from the standard certified limit calculated according to paragraph (b)(2) of this section.

(2) If certified limits are required for impurities, the applicants must propose a certified limit. The standard certified limits may not be used for such substances.

(3) Certified limits should:

(i) Be based on a consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal quality control procedures are used.

(ii) Allow for all sources of variability likely to be encountered in the production process.

(iii) Take into account the stability of the ingredient in the product and the possible formation of impurities between production and sale or distribution.

(4) The applicant may include an explanation of the basis of his proposed certified limits, including how the certified limits were arrived at (*e.g.*, sample analysis, quantitative estimate based on production process), and its accuracy and precision. This will be particularly useful if the range of the certified limit for an active or inert ingredient is greater than the standard certified limits.

(d) *Special cases.* If the Agency finds unacceptable any certified limit (either standard, or applicant proposed), the Agency will inform the registrant or applicant of its determination and will provide supporting reasons. The Agency may also recommend alternative limits to the applicant. The Agency may require, on a case-by-case basis, any or all of the following:

(1) More precise limits.

(2) More thorough explanation of how the certified limits were determined.

(3) A narrower range between the upper and lower certified limits than that proposed.

(e) *Certification statement.* The applicant must certify the accuracy of the information presented, and that the certified limits of the ingredients will be maintained. The following statement, signed by the authorized representative of the company, is acceptable:

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of [*insert product name*], EPA Reg. No. [*insert registration number*], refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

§ 158.355 Enforcement analytical method.

An analytical method suitable for enforcement purposes must be provided for each active ingredient in the product and for each other ingredient or impurity that the Agency determines to be toxicologically significant.

Subpart E—Product Performance

§ 158.400 Product performance data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product performance data requirements for a particular pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop

and aquatic nonfood. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. Data are also required for the general use patterns of forestry use, residential outdoor use, and indoor use, which includes both food and nonfood uses.

(c) *Key.* CR=Conditionally required; NR=Not required; R=Required; EP=End-use product; MP=Manufacturing-use product; TEP=Typical end-use product.

(d) *Table.* The following table lists the data requirements that pertain to product performance. The table notes are shown in paragraph (e) of this section.

TABLE—PRODUCT PERFORMANCE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern									Test substance to support		Test Note No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Residential Outdoor	Indoor	MP	EP	
		Food Crop	Nonfood Crop	Food	Nonfood	Food Crop	Nonfood Crop						
Efficacy of antimicrobial agents													
91–2	Products for use on hard surfaces	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	EP	1
91–3	Products requiring confirmatory data	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	EP	1
91–4	Products for use on fabrics and textiles	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	EP	1
91–5	Air sanitizers	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	EP	1
91–7	Products for control of microbial pests associated with human and animal wastes	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	EP	1
91–8	Products for treating water systems	NR	NR	CR	NR	NR	NR	NR	NR	CR	NR	EP	1
Efficacy of fungicides and nematicides													
93–16	Products for control of organisms producing mycotoxins	CR	NR	CR	NR	CR	NR	NR	NR	NR	NR	EP	1
Efficacy of vertebrate control agents													
96–5	Avian toxicants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
96–6	Avian repellents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96–7	Avian frightening agents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96–9	Bat toxicants and repellents	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	EP	1

TABLE—PRODUCT PERFORMANCE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern									Test substance to support		Test Note No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Residential Outdoor	Indoor	MP	EP	
		Food Crop	Nonfood Crop	Food	Nonfood	Food Crop	Nonfood Crop						
96–10	Commensal rodenticides	R	R	NR	NR	NR	NR	NR	R	R	TEP	EP	1
96–12	Rodenticides on farm and rangelands	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
95–13	Rodent fumigants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95–16	Rodent reproductive inhibitors	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95–17	Mammalian predacides	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1

(e) *Test notes*. The following notes appy to the data requirements table in paragraph (d) of this section.

1. The Agency has waived the requirement to submit product performance data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration.

2. [Reserved]

Subpart F—Toxicology

§ 158.500 Toxicology data requirements table.

(a) *General*. Sections 158.100 through 158.130 describe how to use the data table in paragraph (d) of this section to determine the toxicology data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test in the table are listed in paragraph (e) of this section.

(b) *Use patterns*. (1) Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use, aquatic nonfood use, greenhouse nonfood crop use, forestry use, residential outdoor use, and indoor nonfood use.

(c) *Key*. R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TGAI=Technical grade of the active ingredient; PAI=Pure active ingredient; PAIRA=Pure active ingredient radiolabeled; Choice=Choice of several test substances depending on study required.

(d) *Table*. The following table lists the toxicology data requirements. The table notes are shown in paragraph (e) of this section.

TABLE—TOXICOLOGY DATA REQUIREMENTS

Guideline Number	Data Requirements	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	TGAI and MP	TGAI, EP, and possibly diluted EP	1, 2
870.1200	Acute dermal toxicity	R	R	TGAI and MP	TGAI, EP	1, 2, 3
870.1300	Acute inhalation toxicity - rat	R	R	TGAI and MP	TGAI and EP	4
870.2400	Primary eye irritation - rabbit	R	R	TGAI and MP	TGAI and EP	3

TABLE—TOXICOLOGY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirements	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
870.2500	Primary dermal irritation	R	R	TGAI and MP	TGAI and EP	1, 3
870.2600	Dermal sensitization	R	R	TGAI and MP	TGAI and EP	3, 5
870.6100	Delayed neurotoxicity (acute) - hen	CR	CR	TGAI	TGAI	6
870.6200	Acute neurotoxicity - rat	R	R	TGAI	TGAI	7
Subchronic Testing						
870.3100	90–day Oral - rodent	R	CR	TGAI	TGAI	8, 9
870.3150	90–day Oral - non-rodent	R	CR	TGAI	TGAI	36
870.3200	21/28–day Dermal	R	NR	TGAI	TGAI and EP	10, 11
870.3250	90–day Dermal	CR	R	TGAI	TGAI and EP	11, 12
870.3465	90–day Inhalation - rat	CR	CR	TGAI	TGAI	13, 14
870.6100	28–day Delayed neurotoxicity-hen	CR	CR	TGAI	TGAI	6, 15
870.6200	90–day Neurotoxicity - rat	R	R	TGAI	TGAI	7, 16
Chronic Testing						
870.4100	Chronic oral - rodent	R	CR	TGAI	TGAI	17, 18, 19
870.4200	Carcinogenicity - two rodent species - rat and mouse preferred	R	CR	TGAI	TGAI	9, 17, 18, 19, 20, 21
Developmental Toxicity and Reproduction						
870.3700	Prenatal Developmental toxicity - rat and rabbit, preferred	R	R	TGAI	TGAI	22, 23, 24, 25, 26
870.3800	Reproduction and fertility effects	R	R	TGAI	TGAI	26, 27, 29
870.6300	Developmental neurotoxicity	CR	CR	TGAI	TGAI	27, 28, 29
Mutagenicity Testing						
870.5100	Bacterial reverse mutation assay	R	R	TGAI	TGAI	30
870.5300 870.5375	*In vitro* mammalian cell assay	R	R	TGAI	TGAI	30, 31
870.5385 870.5395	*In vivo* cytogenetics	R	R	TGAI	TGAI	30, 32
Special Testing						
870.7485	Metabolism and pharmacokinetics	R	CR	PAI or PAIRA	PAI or PAIRA	33
870.7200	Companion animal safety	CR	CR	NR	TGAI or EP	34
870.7600	Dermal penetration	CR	CR	Choice	Choice	35
870.7800	Immunotoxicity	R	R	TGAI	TGAI	

(e) *Test notes.* The following test notes apply to the requirements in the table to paragraph (d) of this section:

1. Not required if test material is a gas or a highly volatile liquid.

2. Diluted EP testing is required to support the end product registration if results using the EP meet the criteria for restricted use classification under § 152.170(b) or special review consideration under § 154.7(a)(1).

3. Not required if the test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

4. Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).

5. Required if repeated dermal exposure is likely to occur under conditions of use.

6. Required if the test material is an organophosphorus substance, which includes uncharged organophosphorus esters; thioesters or anhydrides of organophosphoric, organophosphonic, or organophosphoramidic acids; or of related phosphorothioic, phosponothioic, or phosphorothioamidic acids; or is structurally related to other substances that may cause the delayed neurotoxicity sometimes seen in this class of chemicals.

7. As determined by the Agency, additional measurements may also be required, such as cholinesterase activity for certain pesticides, e.g., organophosphates and some carbamates. The route of exposure must correspond with the primary route of exposure.

8. Required for nonfood use pesticides if oral exposure could occur.

9. The 90–day study is required in the rat for hazard characterization (possibly endpoint selection) and dose-setting for the chronic/carcinogenicity study. It is not required in the mouse, but the Agency would strongly encourage the registrant to conduct a 90–day range finding for the purposes of dose selection for the mouse carcinogenicity study to achieve adequate dosing and an acceptable study. The registrant is also encouraged to consult with the Agency on the results of the 90–day mouse study prior to conducting the carcinogenicity study.

10. Required for agricultural uses or if repeated human dermal exposure may occur. Not required if an acceptable 90–day dermal toxicity study is performed and submitted.

11. EP testing is required if the product, or any component of it, may increase dermal absorption of the active ingredient(s) as determined by testing using the TGAI, or increase toxic or pharmacologic effects.

12. Required for food uses if either of the following criteria is met:

(i) The use pattern is such that the dermal route would be the primary route of exposure; or

(ii) The active ingredient is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite is the toxic moiety.

13. Required if there is the likelihood of significant repeated inhalation exposure to the pesticide as a gas, vapor, or aerosol.

14. Based on estimates of the magnitude and duration of human exposure, studies of shorter duration, e.g., 21– or 28–days, may be sufficient to satisfy this requirement. Registrants should consult with the Agency to determine whether studies of shorter duration would meet this requirement.

15. Required if results of acute neurotoxicity study indicate significant statistical or biological effects, or if other available data indicate the potential for this type of delayed neurotoxicity, as determined by the Agency.

16. All 90–day subchronic studies in rats can be designed to simultaneously fulfill the requirements of the 90–day neurotoxicity study using separate groups of animals for testing. Although the subchronic guidelines include the measurement of neurological endpoints, they do not meet the requirement of the 90–day neurotoxicity study.

17. Required if either of the following are met:

(i) The use of the pesticide is likely to result in repeated human exposure over a considerable portion of the human lifespan, as determined by the Agency;

(ii) The use requires a tolerance or an exemption from the requirement of a tolerance.

18. Based on the results of the acute and subchronic neurotoxicity studies, or other available data, a combined chronic toxicity and neurotoxicity study may be required.

19. Studies which are designed to simultaneously fulfill the requirements of both the chronic oral and carcinogenicity studies (i.e., a combined study) may be conducted. Minimum acceptable study durations are:

(i) Chronic rodent feeding study (food use) - 24 months.

(ii) Chronic rodent feeding study (nonfood use) - 12 months.

(iii) Mouse carcinogenicity study - 18 months.

(iv) Rat carcinogenicity study - 24 months.

20. Required if any of the following, as determined by the Agency, are met:

(i) The use of the pesticide is likely to result in significant human exposure over a considerable portion of the human life span which is significant in terms of either frequency, duration, or magnitude of exposure;

(ii) The use requires a tolerance or an exemption from the requirement of a tolerance; or

(iii) The active ingredient, metabolite, degradate, or impurity (a) is structurally related to a recognized carcinogen, (b) causes mutagenic effects as demonstrated by *in vitro* or *in vivo* testing, or (c) produces a morphologic effect in any organ (e.g., hyperplasia, metaplasia) in subchronic studies that may lead to a neoplastic change.

21. If this study is modified or waived, a subchronic 90–day oral study conducted in the same species may be required.

22. Testing in two species is required for all uses.

23. The oral route, by oral intubation, is preferred unless the chemical or physical properties of the test substance or the pattern of exposure suggests a more appropriate route of exposure.

24. Additional testing by other routes may be required if the pesticide is determined to be a prenatal developmental toxicant after oral dosing.

25. May be combined with the 2–generation reproduction study in rodents by utilizing a second mating of the parental animals in either generation.

26. Required to support products intended for food uses and to support products intended for nonfood uses if use of the product is likely to result in significant human exposure over a portion of the human life span in terms of frequency, magnitude or duration of exposure.

27. An information-based approach to testing is preferred, which utilizes the best available knowledge on the chemical (hazard, pharmacokinetic, or mechanistic data) to determine whether a standard guideline study, an enhanced guideline study, or an alternative study should be conducted to assess potential hazard to the developing animal, or in some cases to support a waiver for such testing. Registrants should submit any alternative proposed testing protocols and supporting scientific rationale to the Agency prior to study initiation.

28. Study required using a weight-of-evidence approach considering:

(i) The pesticide causes treatment-related neurological effects in adult animal studies (i.e., clinical signs of neurotoxicity, neuropathology, functional or behavioral effects).

(ii) The pesticide causes treatment-related neurological effects in developing animals, following pre- and postnatal exposure (i.e. nervous system malformations or neuropathy, brain weight changes in offspring, functional or behavioral changes in the offspring).

(iii) The pesticide elicits a causative association between exposures and adverse neurological effects in human epidemiological studies.

(iv) The pesticide evokes a mechanism that is associated with adverse effects on the development of the nervous system (e.g., SAR relationship to known neurotoxicants, altered neuroreceptor or neurotransmitter responses).

29. The use of a combined study that utilizes the 2–generation reproduction study in rodents as a basic protocol for the addition of other endpoints or functional assessments in the immature animal is encouraged.

30. At a minimum, an initial battery of mutagenicity tests with possible confirmatory testing is required. Other relevant mutagenicity tests that may have been performed, plus a complete reference list must also be submitted.

31. Choice of assay using either:

(i) Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression or detection;

(ii) Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgprt) gene locus, accompanied by an appropriate *in vitro* test for clastogenicity; or

(iii) CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xprt) gene locus.

32. The micronucleus rodent bone marrow assay is preferred; however, rodent bone marrow assays using metaphase analysis (aberrations) are acceptable.

33. Required when chronic or carcinogenicity studies are required. May be required if significant adverse effects are seen in available toxicology studies and these effects can be further elucidated by metabolism studies.

34. May be required if the product's use will result in exposure to domestic animals through, but not limited to, direct application.

35. A risk assessment assuming that dermal absorption is equal to oral absorption must be

performed to determine if the study is required, and to identify the doses and duration of exposure for which dermal absorption is to be quantified.

36. A 1–year non-rodent study (i.e., 1–year dog study) would be required if the Agency finds that a pesticide chemical is highly bioaccumulating and is eliminated so slowly that it does not achieve steady state or sufficient tissue concentrations to elicit an effect during a 90–day study. EPA would require the appropriate tier II metabolism and pharmacokinetic studies to evaluate more precisely bioavailability, half-life, and steady state to determine if a longer duration dog toxicity study is needed.

§ 158.510 Tiered testing options for nonfood pesticides.

For nonfood use pesticides only, applicants have two options for generating and submitting required toxicology (§ 158.500) and human exposure (§ 158.1020, § 158.1070, and § 158.1410) studies. Applicants are to select one of the following:

(a) Acute, subchronic, chronic, and other toxicological studies on the active ingredient must be submitted together. The specific makeup of the set of toxicology study requirements is based on the anticipated exposure to the pesticide as determined by the Agency. If hazards are identified based upon review of these studies, specific exposure data will be required to evaluate risk.

(b) Certain toxicological and exposure studies must be submitted simultaneously with the toxicology data submitted in a tiered system. Exposure data must be submitted along with first tier toxicology data. The requirement for additional second and third level toxicology testing will be determined by the Agency based on the results of the first tiered studies.

(1) The required first-tier toxicology studies consist of:

(i) Battery of acute studies.

(ii) A subchronic 90–day dermal study or a subchronic 90–day inhalation study.

(iii) An acute and subchronic neurotoxicity screening battery in the rat.

(iv) Prenatal developmental toxicity studies in both the rat and rabbit.

(v) Reproduction and fertility studies in rats.

(vi) Battery of mutagenicity studies.

(vii) Immunotoxicity study.

(2) The conditionally required second-tier studies include:

(i) Subchronic 90–day feeding studies in both the rodent and nonrodent.

(ii) Dermal penetration study.

(3) The conditionally required third-tier studies include:

(i) Chronic feeding studies in the rodent.

(ii) Carcinogenicity.

(iii) Metabolism study.

(iv) Additional mutagenicity testing.

Subpart G— Ecological Effects

§ 158.630 Terrestrial and aquatic nontarget organisms data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget data requirements for a particular pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood use patterns. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for the general use patterns of forestry and residential outdoor use.

(3) In general, for all outdoor end-uses, including turf, the following studies are required: Two avian oral LD_{50}, two avian dietary LC_{50}, two avian reproduction studies, two freshwater fish LC_{50}, one freshwater invertebrate EC_{50}, one honeybee acute contact LD_{50}, one freshwater fish early-life stage, one freshwater invertebrate life cycle, and three estuarine acute LC_{50}/EC_{50} studies -- fish, mollusk and invertebrate. All other outdoor residential uses, i.e., gardens and ornamental will not usually require the freshwater fish early-life stage, the freshwater invertebrate life-cycle, and the acute estuarine tests.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product; PAI=Pure active ingredient; EP=end-use product. Commas between the test substances (i.e., TGAI, TEP) indicate that data may be required on the TGAI or the TEP depending on the conditions set forth in the test note.

(d) *Table.* The following table shows the data requirements for nontarget terrestrial and aquatic organism. The table notes are shown in paragraph (e) of this section.

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
Avian and Mammalian Testing									
850.2100	Avian oral toxicity	R	R	R	R	CR	CR	TGAI	1, 2, 3
850.2200	Avian dietary toxicity	R	R	R	R	NR	NR	TGAI	1, 4
850.2400	Wild mammal toxicity	CR	CR	CR	CR	NR	NR	TGAI	5
850.2300	Avian reproduction	R	R	R	R	NR	NR	TGAI	1, 4
850.2500	Simulated or actual field testing	CR	CR	CR	CR	NR	NR	TEP	6, 7
Aquatic Organisms Testing									

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
850.1075	Freshwater fish toxicity	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 8, 9, 26
850.1010	Acute toxicity freshwater invertebrates	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 9, 10, 26
850.1025 850.1035 850.1045 850.1055 850.1075	Acute toxicity estuarine and marine organisms	R	R	R	R	NR	NR	TGAI, TEP	1, 9, 11, 12, 26
850.1300	Aquatic invertebrate life cycle (freshwater)	R	R	R	R	NR	NR	TGAI	1, 10, 12
850.1350	Aquatic invertebrate life cycle (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 14, 15
850.1400	Fish early-life stage (freshwater)	R	R	R	R	NR	NR	TGAI	1, 12, 13
850.1400	Fish early-life stage (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 15, 16
850.1500	Fish life cycle	CR	CR	CR	CR	NR	NR	TGAI	17, 18
850.1710 850.1730 850.1850	Aquatic organisms bioavailability, biomagnification, toxicity	CR	CR	CR	CR	NR	NR	TGAI, PAI, degradate	19
850.1950	Simulated or actual field testing for aquatic organisms	CR	CR	CR	CR	NR	NR	TEP	7, 20
Sediment Testing									
850.1735	Whole sediment: acute freshwater invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21
850.1740	Whole sediment: acute marine invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21, 23
	Whole sediment: chronic invertebrates freshwater and marine	CR	CR	CR	CR	NR	NR	TGAI	22, 23
Insect Pollinator Testing									
850.3020	Honeybee acute contact toxicity	R	CR	R	R	NR	NR	TGAI	1
850.3030	Honey bee toxicity of residues on foliage	CR	CR	CR	CR	NR	NR	TEP	24
850.3040	Field testing for pollinators	CR	CR	CR	CR	NR	NR	TEP	25

(e) *Test notes.* The following test notes apply to terrestrial and aquatic nontarget organisms data requirements in the table to paragraph (d) of this section:

1. Data using the TGAI are required to support all outdoor end-use product uses including, but not limited to turf. Data are generally not required to support end-use products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material.

2. For greenhouse and indoor end-use products, data using the TGAI are required to support manufacturing-use products to be reformulated into these same end-use products or to support end-use products when there is no registered manufacturing-use product. Avian acute oral data are not required for liquid formulations for greenhouse and indoor uses. The study is not required if there is no potential for environmental exposure.

3. Data are required on one passerine species and either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. Data are preferred on waterfowl or upland game bird species for indoor and greenhouse uses.

4. Data are required on waterfowl and upland game bird species.

5. Tests are required based on the results of lower tier toxicology studies, such as the acute and subacute testing, intended use pattern, and environmental fate characteristics that indicate potential exposure.

6. Higher tier testing may be required for a specific use pattern when a refined risk assessment indicates a concern based on laboratory toxicity endpoints and refined exposure assessments.

7. Environmental chemistry methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory. Test standards and procedures for independent laboratory validation are available as addenda to the guideline for this test requirement.

8. Data are required on one coldwater fish and one warmwater fish for terrestrial, aquatic, forestry, and residential outdoor uses. For indoor and greenhouse uses, testing with only one of either fish species is required.

9. EP or TEP testing is required for any product which meets any of the following conditions:

i. The end-use pesticide will be introduced directly into an aquatic environment (e.g., aquatic herbicides and mosquito larvicides) when used as directed.

ii. The maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment is ≥ one-half the LC_{50} or EC_{50} of the TGAI when the EP is used as directed.

iii. An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

10. Data are required on one freshwater aquatic invertebrate species.

11. Data are required on one estuarine/marine mollusk, one estuarine/marine invertebrate and one estuarine/marine fish species.

12. Data are generally not required for outdoor residential uses, other than turf, unless data indicate that pesticide residues from the proposed use(s) can potentially enter waterways.

13. Data are required on one freshwater fish species. If the test species is different from the two species used for the freshwater fish acute toxicity tests, a 96–hour LC_{50} on that species must also be provided.

14. Data are required on one estuarine/marine invertebrate species.

15. Data are required on estuarine/marine species if the product meets any of the following conditions:

i. Intended for direct application to the estuarine or marine environment.

ii. Expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

iii. If the acute LC_{50} or EC_{50} < 1 milligram/liter (mg/l).

iv. If the estimated environmental concentration (EEC) in water is ≥ 0.01 of the acute EC_{50} or LC_{50} or if any of the following conditions exist:

A. Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.

B. Physicochemical properties indicate bioaccumulation of the pesticide.

C. The pesticide is persistent in water (e.g., half-life in water > 4 days).

16. Data are required on one estuarine/marine fish species.

17. Data are required on estuarine/marine species if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

18. Data are required on freshwater species if the end-use product is intended to be applied directly to water, or is expected to be transported to water from the intended use site, and when any of the following conditions apply:

i. If the estimated environmental concentration (EEC) is ≥ 0.1 of the no-observed-effect level in the fish early-life stage or invertebrate life cycle test;

ii. If studies of other organisms indicate that the reproductive physiology of fish may be affected.

19. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are < 1,000; or

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is < 5 days at pH 5, 7 and 9.

20. Data are required based on the results of lower tier studies such as acute and chronic aquatic organism testing, intended use pattern, and environmental fate characteristics that indicate significant potential exposure.

21. Data are required if:

i. The half-life of the pesticide in the sediment is ≤ 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

ii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

22. Data are required if:

i. The estimated environmental concentration (EEC) in sediment is > 0.1 of the acute LC_{50}/EC_{50} values and

ii. The half-life of the pesticide in the sediment is > 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

iii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

23. Sediment testing with estuarine/marine test species is required if the product is intended for direct application to the estuarine or marine environment or the product is expected to enter this environment in concentrations which the Agency believes to be significant, either by runoff or erosion, because of its expected use or mobility pattern.

24. Data are required only when the formulation contains one or more active ingredients having an acute LD_{50} of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.

25. Required if any of the following conditions are met:

i. Data from other sources (Experimental Use Permit program, university research, registrant submittals, etc.) indicate potential adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.);

ii. Data from residual toxicity studies indicate extended residual toxicity.

iii. Data derived from studies with terrestrial arthropods other than bees indicate potential chronic, reproductive or behavioral effects.

26. The freshwater fish test species for the TEP testing is the most sensitive of the species tested with the TGAI. Freshwater invertebrate and acute estuarine and marine organisms must also be tested with the EP or TEP using the same species tested with the TGAI.

§ 158.660 Nontarget plant protection data requirements table.

(a) *General.* Sections 158.100 through158.130 describe how to use this table to determine the nontarget plant data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood. The aquatic use pattern includes only the general use patterns of aquatic food crops and aquatic nonfood.

(2) Data are also required for the general use patterns of forestry use and residential outdoor use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product.

(d) *Table.* The following table shows the nontarget plant protection data requirements. The table notes are shown in paragraph (e) of this section.

TABLE—NONTARGET PLANT PROTECTION DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern			Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry and Residential Outdoor		
Nontarget Area Phytotoxicity - Tier I						
850.4100	Seedling emergence	R	R	R	TEP	1, 2, 7
850.4150	Vegetative vigor	R	R	R	TEP	1, 2, 3, 7
850.4400 850.5400	Aquatic plant growth (algal and aquatic vascular plant toxicity)	R	R	R	TEP or TGAI	1, 2, 7
Nontarget Area Phytotoxicity - Tier II						
850.4100	Seedling emergence	CR	CR	CR	TEP	1, 4, 5, 7
850.4150	Vegetative vigor	CR	CR	CR	TEP	1, 3, 4, 5, 7
850.4400 850.5400	Aquatic plant growth (algal and aquatic vascular plant toxicity)	CR	CR	CR	TEP or TGAI	1, 4, 6, 7
Nontarget Area Phytotoxicity - Tier III						
850.4300	Terrestrial field	CR	CR	CR	TEP	1, 7, 8, 10
850.4450	Aquatic field	CR	CR	CR	TEP	1, 7, 8, 10
Target Area Phytotoxicity						
850.4025	Target area phytotoxicity	CR	CR	CR	TEP	1, 7, 9, 10

(e) *Test notes.* The following test notes apply to the table in paragraph (d) of this section.

1. Not required for contained pesticide treatments such as bait boxes and pheromone traps unless adverse effects reports are received by the Agency.

2. Not required for known phytotoxicants.

3. Generally not required for granular formulations. May be requested on a case-by-case basis.

4. Required for known phytotoxicants such as herbicides, desiccants and defoliants.

5. Required if a tested terrestrial species exhibits a 25 percent or greater detrimental effect in the Tier I study. When Tier II testing is required, the test species should be the species that showed detrimental effects in the Tier I testing.

6. Required if the tested aquatic species exhibits a 50 percent or greater detrimental effect in the Tier I study. When Tier II testing is required, the test species should be the species that showed detrimental effects in the tier I testing.

7. Not required for aquatic residential uses.

8. Environmental chemistry methods used to generate data must include the results of a successful confirmatory method trial by an independent laboratory.

9. Tests are required on a case-by-case basis based on the results of lower tier phytotoxicity studies, adverse incident reports, intended use pattern, and environmental fate characteristics that indicate potential exposure.

10. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

Subparts H - J [Reserved]

§§ 158.700 - 158.900 [Reserved]

Subpart K—Human Exposure

§ 158.1000 Applicator exposure—general requirements.

(a) If EPA determines that industrial standards, such as the workplace standards set by the Occupational Safety and Health Administration (OSHA), provide adequate protection from risk under FIFRA for a particular pesticide use pattern, exposure data may not be required for that use pattern. Applicants should consult with the Agency on appropriate testing prior to the initiation of studies.

(b) The Agency may accept surrogate exposure data estimations from other sources to satisfy applicator exposure data requirements if the data meet the basic quality assurance, quality control, good laboratory practice, and other scientific requirements set by EPA. In order to be acceptable, the Agency must find that the surrogate exposure data estimations have adequate information to address applicator exposure data requirements and contain adequate replicates of acceptable quality data to reflect the specific use prescribed on the label and the applicator activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information. The Agency will consider using such surrogate data for evaluating human exposure on a case-by-case basis.

§ 158.1010 Applicator exposure—criteria for testing .

Applicator exposure data described in paragraph (d) of this section are required based on toxicity and exposure criteria. Data are required if a product meets, as determined by the Agency, at least one of the toxicity criteria in paragraph (a) of this section and either or both of the exposure criteria in paragraph (b) of this section.

(a) *Toxicity criteria.* (1) Evidence of potentially significant adverse effects have been observed in any applicable toxicity study.

(2) Scientifically sound epidemiological or poisoning incident data indicate that adverse health effects may have resulted from handling of the pesticide.

(b) *Exposure criteria.* (1) Dermal exposure may occur during the prescribed use.

(2) Respiratory exposure may occur during the prescribed use.

§ 158.1020 Applicator exposure data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the applicator exposure data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Occupational use patterns include products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, terrestrial nonfood crop, aquatic food, aquatic nonfood use, forestry, greenhouse food, greenhouse nonfood, indoor food use, and indoor nonfood use. Occupational use patterns also include commercial (''for hire'') applications to residential outdoor and indoor sites.

(2) Residential use patterns include residential outdoor use and residential indoor use. These use patterns are limited to nonoccupational, *i.e.*, nonprofessional, pesticide applications.

(c) *Key.* R=Required; CR=Conditionally required; TEP=Typical end-use product.

(d) *Table.* The data requirements listed pertain to pesticide products that meet the testing criteria outlined in § 158.1010. The table notes are shown in paragraph (e) of this section.

TABLE—APPLICATOR EXPOSURE DATA REQUIREMENTS

Guideline Number	Data requirement	Use pattern		Test substance	Test Note No.
		Occupational	Residential		
875.1100	Dermal outdoor exposure	R	R	TEP	1, 2, 3
875.1200	Dermal indoor exposure	R	R	TEP	1, 2, 4
875.1300	Inhalation outdoor exposure	R	R	TEP	1, 2, 3
875.1400	Inhalation indoor exposure	R	R	TEP	1, 2, 4
875.1500	Biological monitoring	CR	CR	TEP	1, 2
875.1600	Data reporting and calculations	R	R	TEP	5
875.1700	Product use information	R	R	TEP	--

(e) *Test notes.* The following notes apply to the data requirements in the table to paragraph (d) of this section:

1. Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.

2. Biological monitoring data may be submitted in addition to, or in lieu of, dermal and inhalation exposure data, provided the human pharmacokinetics of the pesticide and/or metabolite/analog compounds (i.e., whichever method is selected as an indicator of body burden or internal dose) allow for the back calculation to actual dose.

3. Data are required if the product is applied outdoors.

4. Data are required if the product is applied indoors.

5. Data reporting and calculations are required when handler exposure data are submitted.

§ 158.1050 Post-application exposure—general requirements.

(a) If EPA determines that industrial standards, such as the workplace standards set by the Occupational Safety and Health Administration, provide adequate protection for a particular pesticide use pattern, post-application exposure data may not be required for that use pattern. Applicants should consult with the Agency on appropriate testing before the initiation of studies.

(b) The Agency may accept surrogate exposure data from other sources to satisfy post-application exposure data requirements if the data meet the basic quality assurance, quality control, good laboratory practice, and other scientific needs of EPA. In order to be acceptable, among other things, the Agency must find that the surrogate exposure data have adequate information to address post-application exposure data requirements and contain adequate replicates of acceptable quality data to reflect the specific use prescribed on the label and the post-application activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information. The Agency will consider using such surrogate data for evaluating human exposure on a case-by-case basis.

§ 158.1060 Post-application exposure—criteria for testing

Exposure data described in § 158.1070(d) are required based upon toxicity and exposure criteria. Data are required if a product meets, as determined by the Agency, either or both of the toxicity criteria in paragraph (a) of this section and either or both of the exposure criteria in paragraph (b) of this section.

(a) *Toxicity criteria.* (1) Evidence of potentially significant adverse health effects have been observed in any applicable toxicity study.

(2) Scientifically sound epidemiological or poisoning incident data indicate that adverse health effects may have resulted from post-application exposure to the pesticide.

(b) *Exposure criteria.* The need for data from potential exposure resulting from situations not covered by this paragraph should be discussed with the Agency.

(1) *For outdoor uses.* (i) Occupational human post-application exposure to pesticide residues on plants or in soil

could occur as the result of cultivation, pruning, harvesting, mowing or other work-related activity. Such uses include agricultural food, feed, and fiber commodities, forest trees, ornamental plants, and turf grass.

(ii) Residential human post-application exposure to pesticide residues on plants or in soil could occur. Such uses may include turf grass, fruits, vegetables, and ornamentals grown at sites, including, but not limited to, homes, parks, and recreation areas.

(2) *For indoor uses.* (i) Occupational human post-application exposure to pesticide residues could occur following the application of the pesticide to indoor spaces or surfaces at agricultural or commercial sites, such as, but not limited to, agricultural animal facilities and industrial or manufacturing facilities.

(ii) Residential human post-application exposure to pesticide residues could occur following the application of the pesticide to indoor spaces or surfaces at residential sites, such as, but not limited to homes, daycare centers, hospitals, schools, and other public buildings.

§ 158.1070 Post-application exposure data requirements table .

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the post-application data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Occupational use patterns include products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, terrestrial nonfood use, aquatic food, aquatic nonfood use, forestry, greenhouse food, greenhouse nonfood, indoor food, and indoor nonfood. Occupational use patterns also include commercial (''for hire'') applications to residential outdoor and indoor sites.

(2) Residential use patterns include residential outdoor use and indoor residential use. These use patterns are limited to nonoccupational, *i.e.*, nonprofessional, pesticide applications.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TEP=Typical end-use product.

(d) *Table.* The data requirements listed in the following table pertain to pesticide products that meet the testing criteria outlined in § 158.1060. The table notes are shown in paragraph (e) of this section.

TABLE—POST-APPLICATION EXPOSURE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern		Test Substance	Test Note No.
		Occupational	Residential		
875.2100	Dislodgeable foliar residue and turf transferable residues	R	R	TEP	1, 2, 3, 4, 5
875.2200	Soil residue dissipation	R	CR	TEP	1, 2, 6, 7
875.2300	Indoor surface residue dissipation	R	R	TEP	1, 2, 8, 9
875.2400	Dermal exposure	R	R	TEP	1, 2, 10, 11, 12
875.2500	Inhalation exposure	R	R	TEP	1, 10, 11, 12
875.2600	Biological monitoring	CR	CR	TEP	1, 12, 13
875.2700	Product use information	R	R	TEP	--
875.2800	Description of human activity	R	R	TEP	--
875.2900	Data reporting and calculations	R	R	TEP	14
875.3000	Nondietary ingestion exposure	NR	R	TEP	1, 11, 15

(e) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (d) of this section:

1. Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.

2. Bridging applicable residue dissipation data to dermal exposure data is required.

3. Turf grass transferable residue dissipation data are required when pesticides are applied to turf grass. Dislodgeable foliar residue dissipation data are required when pesticides are applied to the foliage of plants other than turf grass.

4. Data are required for occupational sites if (i) there are uses on turf grass or other plant foliage, and (ii) the human activity data indicate that workers are likely to have post-application dermal contact with treated foliage while participating in typical activities.

5. Data are required for residential sites if there are uses on turf grass or other plant foliage.

6. Data are required for occupational sites, if (i) there are outdoor or greenhouse uses to or around soil or other planting media, and (ii) the human activity data indicate that workers are likely to have post-application dermal contact with treated soil or planting media while participating in typical activities.

7. Data are required for residential sites if the pesticide is applied to or around soil or other planting media both outdoors and indoors, *e.g.*, residential greenhouse or houseplant uses.

8. Data are required for occupational sites if the pesticide is applied to or around on non-plant surfaces, *e.g.*, flooring or countertops, and if the human activity data indicate that workers are likely to have post-application dermal contact with treated indoor surfaces while participating in typical activities.

9. Data are required for residential sites if the pesticide is applied to or around non-plant surfaces, *e.g.*, flooring and countertops.

10. Data are required for occupational sites if the human activity data indicate that workers are likely to have post-application exposures while participating in typical activities.

11. Data are required for residential sites if post-application exposures are likely.

12. Biological monitoring data may be submitted in addition to, or in lieu of, dermal and inhalation exposure data provided the human pharmocokinetics of the pesticide and/or metabolite/analog compounds (*i.e.*, whichever method is selected as an indicator of body burden or internal dose) allow for a back-calculation to the total internal dose.

13. Data are required when passive dosimetry techniques are not applicable for a particular exposure scenario, such as a swimmer exposure to pesticides.

14. Data reporting and calculations are required when any post-application exposure monitoring data are submitted.

15. The selection of a sampling method will depend on the nondietary pathway(s) of interest. Data must be generated to consider all potential pathways of nondietary ingestion exposure that are applicable (*e.g.*, soil ingestion, hand-to-mouth transfer, and object-to-mouth transfer of surface residues).

Subpart L—Spray Drift

§ 158.1100 Spray drift data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the spray drift data requirements for a particular pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. Data are also required for the general use patterns of forestry use, residential outdoor use, and indoor use.

(c) *Key.* CR=Conditionally required; NR=Not required; TEP=Typical end-use product; MP=Manufacturing use product; EP=End-use product.

(d) *Table.* The following table lists the data requirements that pertain to spray drift. The table notes are shown in paragraph (e) of this section.

TABLE—SPRAY DRIFT DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern									Test substance		Test Note No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Residential Outdoor	Indoor	MP	EP	
		Food Crop	Nonfood Crop	Food	Nonfood	Food Crop	Nonfood Crop						
201–1	Droplet size spectrum	CR	CR	CR	CR	NR	NR	CR	NR	NR	TEP	TEP	1
202–1	Droplet size spectrum	CR	CR	CR	CR	NR	NR	CR	NR	NR	TEP	TEP	1

(e) *Test notes.* The following notes apply to the requirements in the table to paragraph (d) of this section:

1. This study is required when aerial applications (rotary and fixed winged) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. The nontarget organisms include humans, domestic animals, fish and wildlife, and nontarget plants.

2. [Reserved]

Subpart M—[Reserved]

§§ 158.1200 – 158.1299 [Reserved]

Subpart N—Environmental Fate

§ 158.1300 Environmental fate data requirements table.

(a) *General.* All environmental fate data, as described in paragraph (c) of this section, must be submitted to support a request for registration.

(b) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood. The aquatic use pattern includes the general use patterns of aquatic food crop, and aquatic nonfood. The greenhouse use pattern includes both food and nonfood uses. The indoor use pattern includes food, nonfood, and residential indoor uses.

(2) Data are also required for the general use patterns of forestry use and residential outdoor use.

(c) *Key.* CR=Conditionally required; NR=Not required; R=Required; PAIRA=Pure active ingredient radiolabeled; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product.

(d) *Table.* The following table shows the data requirements for environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Greenhouse	Indoor	Forestry	Residential Outdoor		
Degradation Studies - Laboratory									
835.2120	Hydrolysis	R	R	R	CR	R	R	TGAI or PAIRA	1
835.2240	Photodegradation in water	R	R	NR	NR	R	NR	TGAI or PAIRA	2

TABLE—ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Greenhouse	Indoor	Forestry	Residential Outdoor		
835.2410	Photodegradation on soil	R	NR	NR	NR	R	NR	TGAI or PAIRA	3
835.2370	Photodegradation in air	CR	NR	CR	NR	CR	CR	TGAI or PAIRA	4
Metabolism Studies - Laboratory									
835.4100	Aerobic soil	R	CR	R	NR	R	R	TGAI or PAIRA	5
835.4200	Anaerobic soil	R	NR	NR	NR	NR	NR	TGAI or PAIRA	--
835.4300	Aerobic aquatic	R	R	NR	NR	R	NR	TGAI or PAIRA	--
835.4400	Anaerobic aquatic	R	R	NR	NR	R	NR	TGAI or PAIRA	--
Mobility Studies									
835.1230 835.1240	Leaching and adsorption/ desorption	R	R	R	NR	R	R	TGAI or PAIRA	6
835.1410	Volatility - laboratory	CR	NR	CR	NR	NR	NR	TEP	4
835.8100	Volatility - field	CR	NR	CR	NR	NR	NR	TEP	--
Dissipation Studies - Field									
835.6100	Terrestrial	R	CR	NR	NR	CR	R	TEP	5, 7, 12
835.6200	Aquatic (sediment)	CR	R	NR	NR	NR	NR	TEP	7, 8
835.6300	Forestry	NR	NR	NR	NR	CR	NR	TEP	7, 9, 12
835.6400	Combination and tank mixes	CR	CR	NR	NR	NR	NR	TEP	10
Ground Water Monitoring									
835.7100	Ground water monitoring	CR	NR	NR	NR	CR	CR	TEP	7, 9, 11

(e) *Test notes*. The following test notes apply to the requirements in the table to paragraph (d) of this section:

1. Study is required for indoor uses in cases where environmental exposure is likely to occur. Such sites include, but are not limited to, agricultural premises, in or around farm buildings, barnyards, and beehives.

2. Not required when the electronic absorption spectra, measured at pHs 5, 7, and 9, of the chemical and its hydrolytic products, if any, show no absorption or tailing between 290 and 800 nm.

3. Not required when the chemical is to be applied only by soil injection or is incorporated in the soil.

4. Requirement based on use patterns and other pertinent factors including, but not limited to, the Henry's Law Constant of the chemical. In view of methodological difficulties with the study of photodegradation in air, prior consultation with the Agency regarding the protocol is recommended before the test is performed.

5. Required for aquatic food and nonfood crop uses for aquatic sites that are intermittently dry. Such sites include, but are not limited to, cranberry bogs and rice paddies.

6. Adsorption and desorption using a batch equilibrium method is preferred. However in some cases, for example, where the pesticide degrades rapidly, soil column leaching with unaged or aged columns may be more appropriate to fully characterize the potential mobility of the parent compound and major transformation products.

7. Environmental chemistry methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory. Test standards and procedures for independent laboratory validation are available as addenda to the guideline for this test requirement.

8. Requirement for terrestrial uses is based on potential for aquatic exposure and if pesticide residues have the potential for persistence, mobility, nontarget aquatic toxicity or bioaccumulation. Not required for aquatic residential uses. Field testing under the terrestrial field dissipation requirement may be more appropriate for some aquatic food crops, such as rice and cranberry uses, that are managed to have a dry-land period for production. The registrant is encouraged to consult with the Agency on protocols.

9. Agency approval of a protocol is necessary prior to initiation of the study.

10. This study may be triggered if there is specific evidence that the presence of one pesticide can affect the dissipation characteristics of another pesticide when applied simultaneously or serially.

11. Required if the weight-of-evidence indicates that the pesticide and/or its degradates is likely to leach to ground water, taking into account other factors such as the toxicity of the chemicals(s), available monitoring data, and the vulnerability of ground water resources in the pesticide use area.

12. If the terrestrial dissipation study cannot assess all of the major routes of dissipation, the forestry study will be required.

Subpart O—Residue Chemistry

§ 158.1400 Definitions.

The following terms are defined for the purposes of this subpart:

Livestock, for the purposes of this section, includes all domestic animals that are bred for human consumption, including, but not limited to, cattle, swine, sheep, and poultry.

Plant or animal metabolite means a pesticide chemical residue that is the result of biological breakdown of the parent pesticide within the plant or animal.

Residue of concern means the parent pesticidal compound and its metabolites, degradates, and impurities of toxicological concern.

Tolerance, for the purposes of this section, includes the establishment of a new tolerance or tolerance exemption, or amended tolerance or tolerance exemption.

§ 158.1410 Residue chemistry data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the residue chemistry data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Data are required or conditionally required for all pesticides used in or on food and for residential outdoor uses where food crops are grown. Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use.

(2) Data may be required for nonfood uses if pesticide residues may occur in food or feed as a result of the use. Data requirements for these nonfood uses will be determined on a case-by-case basis. For example, most products used in or near kitchens require residue data for risk assessment purposes even though tolerances may not be necessary in all cases.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TGAI=Technical grade of the active ingredient; PAI=Pure active ingredient; PAIRA=Pure active ingredient radio-labeled; Residue of concern= the active ingredient and its metabolites, degradates, and impurities of toxicological concern; TEP=Typical end-use product.

(d) *Table.* The following table list the data requirements for residue chemistry related to food uses. The table notes are shown in paragraph (e) of this section.

TABLE—RESIDUE CHEMISTRY DATA REQUIREMENTS FOR FOOD USES

Guideline Number	Data Requirement	Use Pattern					Test substance	Test Note No.
		Terrestrial Food or Feed	Aquatic Food	Greenhouse Food	Indoor Food	Residential Outdoor		
Supporting Information								
860.1100	Chemical identity	R	R	R	R	R	TGAI	--
860.1200	Directions for use	R	R	R	R	R	--	--
860.1550	Proposed tolerance	R	R	R	CR	NR	--	1
860.1560	Reasonable grounds in support of petition	R	R	R	CR	NR	--	1
860.1650	Submittal of analytical reference standards	R	R	R	CR	NR	PAI and residue of concern	1, 2, 25
Nature of the residue								
860.1300	Nature of the residue in plants	R	R	R	CR	CR	PAIRA	3, 4, 25
860.1300	Nature of the residue in livestock	CR	CR	CR	CR	NR	PAIRA or radiolabeled plant metabolite	1, 6, 25
860.1850	Confined rotational crops	CR	CR	NR	NR	NR	PAIRA	7
Analytical methods								
860.1340	Residue analytical methods	R	R	R	CR	CR	Residue of concern	1, 3, 8, 9, 10, 25
860.1360	Multiresidue method	R	R	R	CR	NR	Residue of concern	1, 11, 25

TABLE—RESIDUE CHEMISTRY DATA REQUIREMENTS FOR FOOD USES—Continued

Guideline Number	Data Requirement	Use Pattern					Test substance	Test Note No.
		Terrestrial Food or Feed	Aquatic Food	Greenhouse Food	Indoor Food	Residential Outdoor		
Magnitude of the residue								
860.1380	Storage stability	R	R	R	CR	CR	TEP or residue of concern	1, 3, 10, 12, 25
860.1500	Crop field trials	R	R	R	CR	CR	TEP	3, 10, 14, 24, 25
860.1520	Processed food or feed	CR	CR	CR	CR	NR	TEP	1, 15, 25
860.1480	Meat/milk/poultry/eggs	CR	CR	CR	CR	NR	TGAI or plant metabolite	1, 16, 17, 18, 25
860.1400	Potable water	NR	R	NR	NR	NR	TEP	19, 25
860.1400	Fish	NR	R	NR	NR	NR	TEP	5, 25
860.1400	Irrigated crops	NR	CR	NR	NR	NR	TEP	20, 25
860.1460	Food handling	NR	NR	NR	CR	NR	TEP	1, 21, 25
860.1540	Anticipated residues	CR	CR	CR	CR	NR	Residue of concern	1, 13, 22, 26
860.1900	Field rotational crops	CR	CR	NR	NR	NR	TEP	23, 25

(e) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (d) of this section.

1. Required if indoor use could result in pesticide residues in or on food or feed.

2. Material safety data sheets must accompany standards as specified by OSHA in 29 CFR 1910.1200.

3. Required for residential outdoor uses on food crops if the corresponding agricultural use is not approved or the residential use is expected to produce higher residues based on the label directions.

4. Required for indoor uses where the pesticide is applied directly to food, in order to determine metabolites and/or degradates. Not required when only indirect contact with food would occur (*e.g.*, crack and crevice treatments).

5. Data for fish are required for all pesticides applied directly to water inhabited, or which will be inhabited, by fish that may be caught or harvested for human consumption.

6. Required when a pesticide is to be applied directly to livestock, to livestock premises, to livestock drinking water, or to crops used for livestock feed. If results from the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be required.

7. Required when the Agency determines that it is reasonably foreseeable that a food or feed crop could be subsequently planted on the site of pesticide application after harvest or failure of the treated crop. Typically not required for pesticide uses in permanent food crops (e.g., various tree crops, vines) or semi-permanent crops (e.g., asparagus, pineapples).

8. A residue analytical method suitable for enforcement purposes is required whenever a numeric tolerance (including temporary and time-limited tolerances) is proposed.

9. New analytical methods to be used for enforcement purposes must include results from an independent laboratory validation.

10. A residue method, storage stability data, and crop field trials are required for the nonfood crop tobacco (green, freshly harvested). Depending on the level of residues found on the green tobacco, additional data may be required on cured/dried tobacco and pyrolysis products.

11. Data are required to determine whether FDA/USDA multiresidue methodology would detect and identify the pesticides and any metabolites.

12. Data are required for any magnitude of the residue study unless analytical samples are stored frozen for 30 days or less, and the active ingredient is not known to be volatile or labile.

13. Studies using single serving samples of a raw agricultural commodity may be needed for acutely toxic pesticides and/or their metabolites. These residue studies must be conducted using a statistical design accepted by the Agency.

14. Required for indoor uses which are direct postharvest treatments of raw agricultural commodities (*e.g.*, fungicidal waxes or stored grain fumigants).

15. Data on the nature and level of residues in processed food/feed are required if residues could potentially concentrate on processing thus requiring the establishment of a separate tolerance higher than that of the raw agricultural commodity.

16. Required when the pesticide use is a direct application to livestock.

17. Data are required if pesticide residues are present in or on livestock feed items or intentionally added to drinking water. These studies, however, may not be required in cases where the livestock metabolism studies indicate negligible transfer of the pesticide's residues of concern to tissues, milk, and eggs at the maximum expected exposure level for the animals.

18. If results from the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock feeding study involving dosing with the plant metabolite(s) may also be required.

19. Data are required whenever a pesticide may be applied directly to water, unless it can be demonstrated that the treated water would not be available for human or livestock consumption.

20. Data are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

21. Data are required whenever a pesticide may be used in a food handling or feed handling establishment.

22. Required when residues at the tolerance level may result in a risk of concern. These data may include washing, cooking, processing or degradation studies as well as market basket surveys for a more precise residue determination.

23. Typically required if pesticide residues of concern greater than 0.01 ppm are found

in crops at the appropriate plant back intervals (taking into account plant back restrictions on product labels) in the confined rotational crop study. If residues of concern in the confined study are greater than 0.01 ppm but less than the limit of quantitation of the analytical method to be used on field trial samples, the Agency will consider not requiring, on a case-by-case basis, the limited field trials. If there are particular toxicological concerns with the parent pesticide or any metabolites, limited field studies may be needed if such residues are identified at levels below 0.01 ppm in the confined study.

24. Crop field trials are required to establish tolerances on rotational crops when quantifiable residues of concern are observed in the field rotational crops study.

25. Not required for an exemption from a tolerance provided that dietary exposure estimates are not needed due to low toxicity or that theoretical estimates of exposure are adequate to assess dietary risk.

26. Not required for an exemption from a tolerance.

Subparts P – T [Reserved]

§§ 158.1500 – 158.1900 [Reserved]

Subpart U—Biochemical Pesticides [Reserved]

§ 158.2000 [Reserved]

Subpart V—Microbial Pesticides [Reserved]

§ 158.2100 [Reserved]

Subpart W—Antimicrobial Pesticides [Reserved]

§ 158.2200 [Reserved]

Subparts X – Z [Reserved]

§§ 158.2300 – 158.2500 [Reserved]

[FR Doc. E7–20826 Filed 10–25–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 158

[EPA–HQ–OPP–2004–0415; FRL–8109–8]

RIN 2070–AD51

Pesticides; Data Requirements for Biochemical and Microbial Pesticides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This is the final rule for Biochemical and Microbial Pesticide Data Requirements. The Agency published a proposed rule on March 8, 2006, on the data requirements to support registration of biochemical and microbial pesticides and proposed to update definitions for both biochemical and microbial pesticides. The Agency received comments from 20 commenters, representing State and Federal agencies, industry, and private consultants.

DATES: This rule is effective on December 26, 2007.

ADDRESSES: EPA has established a docket for this action under Docket identification number EPA-HQ-OPP-2004-0415. All documents in the docket are listed on the regulations.gov web site. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Room S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202. This Docket is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805 .

FOR FURTHER INFORMATION CONTACT: Candace Brassard or Nathanael Martin, U.S. Environmental Protection Agency (7506P), 1200 Pennsylvania Ave., NW., Washington, DC 20460, telephone: 703-305-6598 or 703-305-6475, e-mail: *brassard.candace@epa.gov* or *martin.nathanael@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 producer or registrant of a biochemical or microbial pesticide product. This action may also affect any person or company that might petition the Agency for new tolerances for biochemical or microbial pesticides, or hold a pesticide registration with existing tolerances, any person or company interested in obtaining or retaining a tolerance in the absence of a registration. Potentially affected entities may include, but are not limited to:

- Crop Production (NAICS code 111).
- Animal Production (NAICS code 112).
- Food Manufacturing and Processing (NAICS code 311).
- Chemical Producers (NAICS code 32532), e.g., pesticide manufacturers or formulators of pesticide products, importers, or any person or company that seeks to register a pesticide or obtain a tolerance for a pesticide.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. If you have any questions regarding the applicability of this action to a particular entity, consult the persons listed under **FOR FURTHER INFORMATION CONTACT** or visit the following Web site: *http://www.epa.gov/pesticides/biopesticides/*.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

All documents in the docket are listed in the docket index at *http://www.regulations.gov* under docket number EPA–HQ–OPP–2004–0415. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The hours of operation of this docket facility are from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is 703-305-5805.

II. Overview of This Document

EPA published a notice of proposed rulemaking in the **Federal Register** on March 8, 2006 (71 FR 12072) for Data Requirements for Biochemical and Microbial Pesticides. This document is the final rule and the response to comments on the proposed rule. EPA received comments from 20 commenters, raising 58 comments on various data requirement issues for biochemical and microbial pesticides. A total of 11 comments concerning the definition of a biochemical pesticide and 5 comments concerning the

definition of a microbial pesticide were received. Of the 20 commenters, 15 were from industry or private consulting firms, 4 were from State/Federal/international governments, and 1 was from a public interest group.

In response to comments, EPA is modifying some aspects of the rule relating to types of products being tested, i.e., technical grade active ingredient (TGAI) versus typical end-product (TEP), modifying some test notes where appropriate, adding or deleting some data requirements, and modifying the definition of a microbial pesticide.

The final rule updates the definitions of a biochemical pesticide and a microbial pesticide to more accurately describe these categories of pesticides, and to make a conforming change to the definition of microbial pesticide in 40 CFR 172.43. The rule also informs the public how the Agency will assist applicants in determining what data are appropriate to support registration of a biochemical or microbial pesticide. EPA encourages applicants to request pre-submission meetings to discuss these data issues. The final rule also provides for assistance to applicants, in some narrow circumstances, in preparation of an applicant's data waiver.

As an ancillary matter, this final rule is making certain technical changes necessitated by EPA's decision to create new part 161 to contain data requirements specific to antimicrobial pesticides. New part 161 is discussed fully in the final rule for conventional pesticides published elsewhere in this issue of the **Federal Register**. By transferring essentially intact the current part 158 requirements, EPA would also be transferring material pertaining to biochemical and microbial pesticides that is not intended to be covered by part 161. Specifically, EPA is removing §§ 161.65, 161.690 and 161.740, the freestanding sections devoted exclusively to biochemical and microbial pesticides.

This final rule is one in a series of proposed and final rules to update and clarify pesticide data requirements.

III. The Proposed Rule and Related Proposal for Conventional Chemicals

On March 8, 2006, the Agency published a notice of proposed rulemaking for Biochemical and Microbial Pesticide Data Requirements (71 FR 12072). The Agency received submissions from 20 commenters. This final rule describes briefly the background of the final rule and responds to key issues raised by commenters.

A. General Background on the Phased Rulemaking Approach

EPA is responsible for registration of the following categories of pesticides: biochemicals, microbials, plant-incorporated protectants, conventional pesticides, and antimicrobial pesticides. These pesticides, although regulated under the same statutory standards under FIFRA and FFDCA, pose different levels of risk and exposure that lead to significant differences in data needs. EPA has embarked on a series of rulemakings intended to update data requirements for the various types of pesticides. This final rule is the second and builds on the previous update for conventional chemicals.

Elsewhere in this issue of the **Federal Register** EPA published a final rule to update and revise its data requirements for the registration of conventional pesticides. In addition to specific changes to the data requirements for registration of conventional pesticides, EPA made a number of other changes to the general provisions of part 158. Specifically, subpart A of the rule for conventional chemicals describes general provisions including definitions, format of data submissions, policies on Confidential Business Information (CBI), flagging criteria, waivers, and minor uses. Subpart B of the rule for conventional chemicals describes expanded use patterns, clarifications on using the data tables, identifying data for Experimental Use Permits (EUPs), test guidelines, and purpose of the registration data requirements.

EPA proposed to also upgrade the structure of part 158, assigning biochemical data requirements to subpart L and microbial pesticide data requirements to subpart M of part 158. As a result of the comments on the proposed rule for conventional pesticides, EPA has restructured part 158. Biochemical pesticide data requirements will now be under subpart U and microbial pesticide data requirements will be under subpart V.

B. General Provisions and Format

As described in the final rule on Conventional Pesticides published elsewhere in this issue of the **Federal Register**, EPA has reorganized and reformatted part 158, subpart A (General Provisions) and subpart B (How to Use Data Tables), and reorganized and redesignated subpart D (Data Requirement Tables) into a number of individual subparts.

Many of the revisions are intended to improve the usefulness of part 158 data tables by better identifying the specific data requirements that could apply to a particular pesticide application. As with the original design of part 158 in 1984, given the variety in pesticide chemistry, exposure, and hazard, these revisions are intended to retain a fair amount of flexibility in their application, while improving clarity and transparency to the regulated community.

C. Required and Conditionally Required Data Requirements

As with conventional pesticides, the R/CR terminology is a general presentation of the likelihood that a data requirement will apply. The use of R does not necessarily indicate that a study is always required, but that it is more likely to be required than not. The use of CR means a study is less likely to be required. However, both R and CR designations must be read in the context of the accompanying test notes to the table. An applicant may assume that a data requirement with R will typically be required all the time. The test notes accompanying that R designation may provide supplementary information or identify some condition(s) when the study is not required. A CR designation will generally include more extensive test notes describing the limited conditionality of the requirement. The final rule continues this longstanding practice. EPA revised some of the test notes to clarify the conditions under which the data would be required.

IV. Regulation of Biochemical and Microbial Pesticides and Response to Comments Discussion

A. Background of Regulating Biochemical and Microbial Pesticides

This document is the final rule for the Biochemical and Microbial Pesticide Data Requirements. This document also finalizes definitions of both a biochemical and microbial pesticide. The Agency issued a Notice of Proposed Rulemaking on Biochemical and Microbial Pesticide Data Requirements, 71 FR 12072; March 8, 2006. This notice was an update of the biochemical and microbial pesticide data requirements to support the registration of biochemical and microbial pesticides originally promulgated in 1984.

B. Consultations with Applicants

In the preamble to the proposed rule, the Agency discussed a process for consultations with applicants. The public responses were in favor of the Agency recognizing that applicants often needed assistance in determining what information or data are appropriate to support registration of a biochemical or microbial pesticide.

Therefore, EPA will continue to encourage applicants to request pre-submission meetings to discuss these data issues. EPA will also continue to provide assistance to applicants in some narrow circumstances in preparation of an applicant's data waiver after submission of an application.

EPA encourages applicants to seek pre-submission meetings to discuss the appropriate data or information to support their product and the opportunity for requesting data waivers. During the pre-submission meeting, EPA may be aware that certain data requirements are already satisfied by available data or information. Sources of existing data include public literature and/or studies submitted by another registrant, which may be cited by the applicant in accordance with relevant data compensation procedures. EPA may also be aware of sound scientific rationales that render certain testing unnecessary. Ultimately, the applicant may submit an application based on the discussion with EPA, along with a signed copy of the minutes (which have been concurred on by the Agency) of the pre-submission meeting listing each data requirement and the reason why EPA and the company believe a waiver is appropriate.

In addition, the Agency is offering a post-submission process. Even after submission of an application for registration, EPA may find that either of these scenarios may exist (i.e., basis for citing to other data or information, or waiver of a data requirement). Again, EPA may discuss these issues with the applicant and the applicant may choose to amend its application by citing to other data/information or requesting a waiver.

This pre-submission and post-submission process for ensuring that the data requirements are either satisfied or waived is specific to the review of biochemical and microbial registration applications, due primarily to the specific nature and circumstances unique to these pesticides (e.g., information already known to the Agency) and thus the Agency does not anticipate this process being widely applicable to other types of pesticides, such as conventional or antimicrobial pesticides.

EPA notes that in providing this assistance during the pre-submission and post-submission process, it will only consider readily accessible information, such as information found in Agency databases, and will not search for applicable information, data, or literature. Further, although this process is intended to help applicants in supporting their applications, EPA does not encourage applicants to rely on this process to fill informational data gaps; doing so may be at the expense of timely review or may ultimately result in rejection of an application or petition.

Finally, providing assistance in this manner does not effectively allow applicants to circumvent the data requirements or the requirement to submit a request for waiver of a data requirement. The applicant must at all times submit the waiver request; EPA is simply providing assistance in identifying what requirements are likely to be waived for a particular product or, in some narrow circumstances, assistance in the preparation of the waiver request. Because we are using the pre-and post-submission process to assist applicants in filing their own waiver requests, we are not amending the existing waiver provisions at 40 CFR 158.45.

C. Agency Coordination with the APHIS Permitting Process

EPA requested comment on whether the Agency should coordinate with USDA for reviewing microbial pesticides prior to registration. The Agency was prompted by USDA's need for coordination when an Animal and Plant Health Inspection Service (APHIS) movement permit under 7 CFR part 340 is needed. USDA suggested that registrants be required to submit a copy of the applicable APHIS permits as part of the registration application to EPA. After discussing this issue with USDA, EPA is developing a process for coordinating the review of these applications with USDA to avoid delays.

D. Other Issues

With respect to some of the environmental fate data requirements, the Agency is providing two sets of guideline numbers where needed; the first guideline numbers are those currently used by the Agency. The second guideline numbers, which are in parentheses, are the draft guidelines that have completed peer review and will be published as EPA final guidelines in the near future. Guideline numbers are provided in part 158 as information/guidance to applicants, and both guideline numbers are provided for each data requirement in this rule as an interim measure until the draft guidelines are finalized. In general, draft guidelines do not represent official Agency position until finalized. In either case, an applicant is not compelled to use the cited guidelines, but may choose to use an alternative methodology that will provide the information needed to complete the risk assessment. In such cases, applicants are encouraged to consult with EPA beforehand. Applicants may also consult with EPA about using an alternative methodology in draft guideline that has completed peer review.

As with the existing guidelines, draft guidelines are developed through a rigorous scientific process, including public comment and extensive peer review by the Scientific Advisory Panel, and many have been harmonized internationally. As such, they represent the Agency's recommended approach to developing data that will generally be likely to satisfy the Agency's data needs for risk assessment, and an applicant choosing to use the Agency guidelines may have greater confidence that the resulting data will adequately address our needs. This may also be the case for the draft guidelines referenced in parentheses in this rule. Once finalized, the Agency would correct the guideline references as appropriate.

E. Issues Identified that Apply to Both Biochemical and Microbial Pesticide Data Requirements.

The Agency did receive comments that applied to both biochemical and microbial pesticide data requirements. These issues are discussed as follows:

1. *Endangered species assessments—summary of comments.* Incidental to its proposed data requirements for conventional pesticides, EPA discussed the possibility of future data and information needs to develop and/or refine risk assessments for endangered species. EPA did not propose any data requirements specific to endangered species but described its current level of information and data usage. EPA requested comment on the value and utility of location and usage information, and on additional types of research that might yield greater refinement in risk assessments for endangered species. One commenter questioned whether the Agency's endangered species discussion in the preamble applies to biochemical and microbial pesticides only, or for conventional pesticides as well. Two commenters indicated the Agency should require toxicity data for surrogate species, and in particular reptile and amphibian data.

Summary of response to comments. EPA appreciates the responses it received from the commenter on this topic. As endangered species data requirements were not proposed, EPA has not responded to the comment as part of this final rule but will consider them in the context of its ongoing risk assessments. If EPA finds that it needs

to amend part 158 to normalize endangered species data requirements, the Agency will consider these comments in the development of a future proposed rule. The Agency has in the past and will continue to rely on the avian, fish, and invertebrate testing to indicate the potential toxicity for other non-target species.

2. *Product performance—summary of comments.* Without proposing changes to existing product performance data requirements (§ 158.640), the Agency augmented language for both biochemical and microbial pesticide data requirements for product performance with the regulatory text. One commenter indicated that the Agency requires data for uses other than for public health pests. Another comment was that EPA's language in the proposed preamble required clarification, indicating some products are not as efficacious as conventional pesticides. Another commenter indicated that the label should be supported by the efficacy data provided to the Agency.

Summary of response to comments. The Agency agrees that product performance data are required for all uses, but are only required to be submitted for review at the time of registration to support public health claims. These provisions, i.e. new §§ 158.2070 and 158.2160 for biochemical and microbial pesticides, respectively, are not replacing the data requirement tables in § 158.640, but only adding additional text for clarifying when submission of product performance data are typically necessary for biochemical and microbial pesticides. EPA is finalizing the language as proposed. EPA agrees with the commenters that the data must be submitted to support the label claims for registration of these public health pesticides.

EPA did not propose to change the existing data requirements and neither the existing data table nor the proposed regulating text would require the applicant to submit data comparing product efficacy. The Agency agrees with the commenter that there should not have been a distinction between biochemical and conventional pesticides in their efficacy, but that the efficacy varies between all pesticides and their products, and with respect to public health claims, the label should reflect the efficacy of the product.

3. *Addition of passerine species and appropriate nomenclature of test species within nontarget ecological effects data requirements—summary of comments.* The Agency proposed to add another possible test species for the avian acute oral toxicity study, the red-winged blackbird, a passerine species. EPA also proposed to continue to include the identification of other possible avian test species (bobwhite quail and mallards), and for fish species (rainbow trout and bluegill sunfish). One commenter requested that EPA revise the word ''songbird'' to read ''passerine.'' Another commenter indicated that the Agency should require historical control data on the red-winged blackbird for the past 5 years to develop a baseline for future testing on the species.

Summary of response to comments. The Agency recommends that if the registrant and the Agency deem it appropriate to test a passerine species, the registrant meet with the Agency before initiating the study to determine if the passerine species is appropriate based on the current scientific methodology and use pattern of the proposed registration. This test species may be required if the use pattern would result in higher exposure to this order of avian species.

In addition, after reviewing the comments submitted, the Agency decided to discontinue specific species designation for all non-target organisms. The test notes in the final rule only indicate upland game, waterfowl, or passerine species for avian concerns and coldwater and warmwater fish for fish concerns.

In summary, passerine species data are still conditionally required in the final rule for both biochemical and microbial pesticides. The individual test notes indicate when these data would be appropriate. With respect to developing test data over 5 years, EPA will consider such protocol concerns when it revises its test guidelines. The Agency is finalizing the proposed addition of the passerine species.

4. *Reptile/amphibian testing—summary of comments.* The Agency did not propose to require separate reptile testing. One commenter indicated that amphibian testing needed to be included in the data requirements for evaluating effects to non-target ecological species.

Summary of response to comments. The Agency has in the past and will continue to rely on avian, fish, and invertebrate testing to indicate the potential toxicity for other non-target species. Additional information will be required as needed.

5. *New studies providing little or no practical value— summary of comments.* EPA proposed to require a few newly codified studies, i.e., applicator/user exposure data to refine data requirements, i.e., mutagenicity data requirements. One commenter believed the Agency was using a ''check box'' approach to requiring data rather than regulatory need.

Summary of response to comments. The Agency reviewed the data typically submitted or determined to be necessary to support registration requests received over 7 years. EPA's proposed rule was based on that review. In some cases, EPA proposed new data requirements to codify existing practices and in other cases EPA proposed to amend test notes, for example, to clarify existing data requirements. EPA's analysis and proposed rule were based on decisions that the data and the modifications to the tables were necessary. Without more specific comment, EPA can not further respond to this comment.

6. *Providing adequate guidance when data are required/use pattern clarification—summary of comments.* When EPA revised the proposed rule, there was a concerted effort to provide informative test notes, which would clarify when data are required. However, a commenter did not provide specific data requirement issues but indicated the Agency was not clear on the expanded use patterns. This commenter also indicated that the waiver policy was unclear.

Summary of response to comments. As indicated earlier in this preamble, the Agency provided a section on ''Consultation with Applicants'' in the proposal which the commenter indicated was missing. It is a description of the pre-submission and post-submission process within the Agency encouraging the registrant to meet with the Agency as early as possible in the process in order to minimize delays and avoid unnecessary test costs. In most cases the numbers of use patterns were actually combined for transparency, i.e., food use and non-food use. The test notes provided for biochemical and microbial pesticides are more detailed than in the current regulation.

7. *There are no accepted protocols or guidelines for many data requirements—summary of comments.* One commenter indicated that the Agency published data requirements without supporting published guidelines. This commenter cited the environmental fate guidelines.

Summary of response to comments. The Agency proposed newly codified data data requirements guidelines for applicator/user exposure data; particle size, fiber length, and diameter distribution; product use information; and companion animal safety. There were also some new guideline numbers identified for environmental fate data

requirements. All of these data requirements have guidelines available. At the time of the publication of the proposed rule, the environmental fate guidelines were not finalized. The Agency did provide the existing guideline numbers that denoted the test methods at that time. The environmental fate guidelines (835 series) are anticipated to be published this year. In the interim, we have provided the current guideline numbers and the proposed guideline numbers in the data table. Once the final guidelines are published, the Agency will amend the Guideline references in the datea tables, as appropriate. As indicated previously, the guideline references are provided in part 158 as information/guidance to applicants. As with existing guidelines, an applicant is not compelled to use the cited draft guidelines, but may choose to use an alternative methodology that will provide the information needed to complete the risk assessment. (See Unit IV.D.).

8. *Codifying existing practice—summary of comments*. EPA made revisions, which included codified, newly codified, or new data requirements. One commenter stated that the Agency was mistaken in its distinction between ''new requirements'' and ''newly codified requirements.'' The commenter provided the example that the immunotoxicity study (guideline 885.3550), is a new requirement, as no such data requirement previously existed, regardless of whether the guideline was available.

Summary of response to comments. In developing this rule, the Agency received the data typically submitted or determined to be necessary to support registration requests received over the last 7 years. If the data had never been submitted to support registration, then the data requirement would be considered new. However, if the data had been submitted or required to support recent registrations, and were not listed in the 1984 promulgated rule, then the Agency would classify that data requirement as newly codified.

As for the specific example of immunotoxicity, these data are currently required and are being submitted to support existing registrations and is currently required in 40 CFR 158.690. EPA has been requiring or applicants have been submitting immunotoxicity data based on specific conditions, consistent with the 880.3550 guideline in more recent years, so the Agency classified this as a newly codified data requirement as a Tier II and Tier III data requirement.

9. *Animal welfare concerns—summary of comments*. The Agency received comment on individual studies suggesting alternative approaches to substitute for them. This comment was designed to recommend reducing the number of animals used in studies.

Summary of response to comments. All new studies required under today's rule for biochemical and microbial pesticides were all standard guideline studies that are also part of the data requirements for conventional pesticides. The EPA's Biopesticides and Pollution Prevention Division (BPPD) uses, where possible, the same studies that are used for conventional pesticides to allow for similar risk assessment procedures; to support the validated, time-tried, methods; to reduce the complexity of studies that testing laboratories must provide; to avoid excessive expenses for the typically small businesses that market these biopesticides; and to avoid instituting novel, non-validated procedures for a relatively small group of pesticides. As discussed in the preamble to the final rule for the data requirements for the registration of conventional pesticide products, Unit XIII, Discussion of Comments on Animal Welfare Concerns, the Agency is committed to avoiding unnecessary animal testing, while taking into consideration principles of sound science and the requirements of FIFRA to protect humans and the environment. The complete Unit XIII response to these comments also applies to microbial and biochemical pesticide data requirements. BPPD will consider test methods that do not use animals and is working with the rest of the Agency to move towards these goals. In addition, BPPD will continue to be available for pre and post submission meetings to allow an applicant to submit only those data needed to support that particular product.

V. Biochemical Pesticide Data Requirements (new Subpart U)

A. Definition of Biochemical (§ 158.2000)

Summary of proposed definition. EPA proposed to revise the definition of biochemical pesticide and received 11 comments on the definition. EPA's proposed definition was as follows:

A biochemical pesticide is a pesticide that:

(1) Is a naturally-occurring substance or structurally similar and functionally identical to a naturally-occurring substance;

(2) Has a history of exposure to humans and the environment demonstrating minimal toxicity, or in the case of a synthetically derived biochemical pesticide, is equivalent to a naturally-occurring substance that has such a history; and

(3) Has a non-toxic mode of action to the target pest(s).

As explained in the proposed rule, EPA proposed to clarify the ''naturally-occurring'' clause of the prior definition by adding a criterion that the pesticide have a history of exposure demonstrating minimal toxicity. EPA believes that if a pesticide is present in the environment in sufficient quantities, there would be a good chance that any innate toxicity would already have been recognized due to observed effects on humans or representative non-target organisms. A pesticide that meets this, as well as other specified criteria, is more appropriate for the tiering data structure that EPA uses for biochemicals than a pesticide that does not have such history of exposure or a pesticide that has a history of exposure in which such exposure has revealed toxicity concerns.

The tiering structure can be beneficial if data submitted to satisfy the early tiers allow EPA to determine that the pesticide does not cause unreasonable adverse effects on the environment. This determination at the early tiered stage can reduce the total amount of data generated to satisfy registration as compared to pesticides that do not meet the biochemical definition.

If the pesticide is naturally occurring but otherwise does not clearly meet the biochemical definition, EPA is not likely to use the biochemical pesticides tiering structure for testing; instead, EPA would likely apply the data requirements for conventional pesticides for an adequate assessment of the risks from the proposed use of such a pesticide. However, note that in some limited cases, EPA may assess a pesticide under the biochemical pesticide tiering structure even though the pesticide is not a biochemical pesticide. Specifically, EPA added paragraph (c) to 40 CFR 158.2000 to allow some limited use of the biochemical tiering structure for pesticides not clearly meeting the biochemical definition but for which only minimal additional data would be necessary. Please refer to the preamble of the proposed rule for further explanation.

EPA also proposed that to meet the definition of ''biochemical'' the pesticide must have a non-toxic mode of action to the target pest. EPA proposed this criterion to conform to the original intent for defining biochemical, that the term describes a pesticide that is ''not the result of target organism

toxification.'' As EPA explained in the proposed rule, the natural occurrence of a pesticide does not necessarily mean that it has a non-toxic mode of action to the target pest. An example might be pyrethrins, which are naturally-occurring toxins that occur in chrysanthemum plants. See the proposed preamble and regulatory text for a more complete discussion of the proposed definition.

Summary of comments. Eleven commenters identified concerns for the revised definition of a biochemical pesticide. In particular, the commenters believed in most cases that the proposed definition was more restrictive than the current definition. Of particular concern was the addition of the criterion that a biochemical pesticide must have a non-toxic mode of action. A suggestion was made that the definition be reworded to include the phrase ''mitigating mode of action'' as in ''Has a non-toxic or mitigating mode of action to the target pest.'' The commenters suggested that this would allow inclusion of a physical mode of action. Another commenter indicated that the new definition would not allow pesticides that cause suffocation.

In addition, most of these commenters believed that the proposed definition, which included the language ''Has a history of exposure ... demonstrating minimal toxicity'' and ''Has a non-toxic mode of action to the target pest(s),'' would also make the criteria for defining a biochemical more restrictive, possibly disallowing insect pheromones, juvenile growth hormones, and most plant and animal extracts to be classified as biochemical pesticides. One commenter indicated that the definition should include both natural occurrence and non-toxic mode of action as part of the definition for low risk.

One commenter generally supported the new definition but suggested that EPA also consider setting some limits to exposure since some naturally-occurring substances may be much more toxic if their use patterns result in high exposure levels. Another commenter expressed a concern that saponins would not be considered as biochemical pesticides under the proposed definition.

Summary of response to comments. EPA disagrees with the general comment that the proposed definition is more restrictive than EPA's operation under the prior definition. EPA reviewed all 180 biochemical pesticide registrations since 1948 and determined that only two pesticides currently evaluated as biochemicals would not fit the definition of a biochemical pesticide as proposed. Though these two have been evaluated as biochemical pesticides, the data required were equivalent to what was required to support conventional pesticides. Based on this survey of biochemical pesticides, the Agency expects that there will be no significant differences in the scope of pesticides EPA evaluated as biochemical pesticides prior to the effect of this rule and the scope of those EPA evaluates as biochemical pesticides under this new definition. This applies equally to the scope of insect pheromones, juvenile growth hormones, and plant and animal extracts evaluated under the prior definition and that would be evaluated under the new definition.

The Agency would like to clarify that the provision that a biochemical pesticide is a naturally-occurring substance as well as a compound that is structurally-similar and functionally identical to a naturally-occurring substance, also applies to pheromones. The pheromone definition in today's rule has been modified to make this explicit. In addition, the straight chain lepidopteran pheromone definition will be slightly corrected to correspond with the internationally-recognized definition as used in the tolerance exemption at § 180.1153. The word ''double'' is added to ''three bonds'' to read as ''three double bonds''. The Agency is also replacing ''designated by'' with ''consisting of'' in order to make the definition more transparent. The revised definition will read: '' A straight chain lepidopteran pheromone is a lepidopteran pheromone consisting of an unbranched aliphatic chain (between 9 and 18 carbons) ending in an alcohol, aldehyde, or acetate functional group and containing up to three double bonds in the aliphatic backbone.''

EPA does not believe that the recommended inclusion of a ''mitigating mode of action'' is needed. First, the Agency interprets the phrase ''non-toxic mode of action'' to include such pest control mechanisms as attraction, repellency (including irritants), growth regulation/development changes, induction of systemic acquired resistance, and physical modes of action such as desiccation, coatings, or smothering, e.g., by naturally-occurring oils. The Agency recognizes that physical modes of action, e.g. suffocation, may be lethal to the target pest, but since they do not involve toxic chemical/poison-induced effects in the context of this program, they are considered to be a non-toxic mode of action. This is how EPA has interpreted ''unique modes of action'' as used in the prior definition. EPA notes that the Biochemical Classification Committee (consisting of EPA scientists) was formed in 1995 and has been responsible for determining whether a proposed pesticide is eligible to be evaluated as a biochemical pesticide and has consistently applied this interpretation of the existing definition. EPA proposed to include the phrase ''non-toxic mode of action'' instead of the phrase ''unique modes of action'' because EPA believes the former and proposed phrase better/more accurately describes our historical approach for defining ''biochemical pesticides,'' and intended no change in the scope of the term historically applied. In addition, to the fact that the proposed phrase captures commenter's concern, commenters did not adequately define the word ''mitigate'' as it would apply to pesticidal modes of action. Thus, EPA believes using a reference to mitigating mode of action is unnecessary and may only add confusion in implementation.

Finally, for practical reasons, EPA does not believe that setting a limit based on the amount of existing exposure as compared to that contemplated by the proposed use pattern is necessary as recommended by the commenter. Implementation of this concept would be very difficult since the classification of the product would depend on the uses proposed with the initial application, which often change subsequent to the risk assessment process. It would be impractical to have to reclassify an active ingredient from a biochemical pesticide to a chemical pesticide based on use patterns. In practice, EPA will initially classify a pesticide as a biochemical pesticide, but will apply additional data requirements, up to and including those for conventional pesticides, to adequately assess the risk. In no case will an initial determination of biochemical status preclude the Agency from requiring data not specifically included in subpart U if necessary.

Another commenter stated the belief that saponins (naturally-occurring glycosides within plants) should be considered biochemical pesticides and that the new definition precludes such a finding. The Agency believes not all saponins would necessarily be registered as biochemical pesticides. Each one has to be evaluated carefully. This illustrates the importance of having sufficient exposure of naturally occurring chemicals to determine if any unreasonable toxicity is observed. Some saponins are known to be poisonous to people if swallowed, and some saponins can cause severe dermal irritation, and others may not be absorbed at low levels in the diet. Many saponins are

especially toxic to fish. Any changes in the application or scope of the definition would be addressed through notice and comment rulemaking.

B. Individual Biochemical Data Requirements

As noted in Unit II, 20 commenters responded to the proposal. The following sections are responses to comments raised:

1. *TEP and EP testing versus TGAI testing—summary of comments.* Many commenters raised concerns about the variability in test material used for testing typical end-use product (TEP) or end-use product (EP) or technical grade active ingredient (TGAI) and whether to require the use of the same test material as that required for conventional pesticide data requirements.

Summary of response to comments. The Agency compared the test materials required for conventional pesticides and determined that requiring the same testing material (i.e., TEP, EP, or TGAI) for biochemical pesticides to be used is appropriate in some circumstances. However, upon review EPA determined that there are instances where the types of testing material should not be the same. This difference is because there usually is no ''typical end-use product'' for biochemical pesticides. Most biochemical pesticide EPs are difficult to replicate. Therefore, TGAI is being required for many instances in which the conventional pesticide regulations require TEP or EP. EPA has made revisions where appropriate in the final rule.

2. *Particle size, fiber length, and diameter distribution—summary of comments.* EPA proposed to add a new requirement for particle size, fiber length and diameter distribution, due to spray drift concerns. This new data requirement is consistent with conventional pesticides data requirements with the exception of the test material to be used; the Agency is requiring TGAI data for biochemical pesticides given the difficulties of producing a replicated TEP or EP. One commenter questioned the need for this data requirement.

Summary of response to comments. As indicated in the proposed preamble, the data from these studies are needed to complete the environmental fate assessment to estimate the potential pesticide drift to non-target areas. The Agency should have included in the justification that these data are also useful for determining the potential for acute inhalation toxicity to human health and the environment. The Agency is being consistent with its assessment, since it reached the same conclusion in response to comments for conventional pesticides.

Specifically, particle size is generally expressed as mean mass aerodynamic diameter (MMAD), which is a practical way to account for the different possible shapes such as fibers, clumps, etc. The particle size distribution is used as a set of criteria to determine respirability for purposes of establishing the need and/or the acceptability of inhalation toxicity studies (acute and, if the main route of exposure is inhalation, subchronic toxicity studies), and again, these data can also be used for spray drift evaluation.

3. *Immunotoxicity data requirements—summary of comment.* EPA proposed to move the immune response requirements from Tier I and Tier II to Tier II and Tier III and added two test notes indicating when the data are required. One commenter stated immunotoxicity tier II data are difficult to interpret. Another commenter believed that this should be identified as a ''new requirement'' rather than as ''codifying an existing data requirement.''

Summary of response to comments. EPA is finalizing the amendments as proposed. The name of this study has changed, but the ''immunotoxicity testing'' data requirement is identical to the original ''immune response'' testing. To provide more guidance on when the studies are actually required, the final rule includes two test notes. As a result the data will be conditionally required as Tier II and Tier III data requirements.

4. *Companion animal safety data requirement—summary of comments.* The Agency proposed to add companion animal safety data requirements based on past experiences indicating the data were needed for a risk assessment. One commenter requested that the Agency define companion animal species and surrogate species to be tested.

Summary of response to comments. The Agency did not define the species to be tested in a test note since it relies on the Pesticide Assessment Guidelines (870.7200) to identify various appropriate species, which traditionally have been required to support flea and tick treatments for pets (i.e., dogs and cats). EPA has not changed the final rule as a result of the comments received, except we provided more specific guidance on test substance, (i.e., TGAI instead of choice).

5. *Applicator/user exposure data requirements—summary of comments.* EPA proposed to add data requirements to address applicator/user exposure. EPA proposed a series of data requirements within this category to be tested on TGAI. EPA proposed to require background information as part of the applicator/user exposure monitoring data requirements. One commenter requested that EPA clarify its expectation that applicator exposure data requirements are primarily intended to generate data to support evaluation of insect repellents. One commenter indicated these data were not needed for all use patterns.

Summary of response to comments. EPA has decided to not finalize its proposal to require background information for the applicator/user exposure monitoring test (guideline 875.1000) since the same data are already required to be submitted under the various other data requirements, i.e., dermal outdoor exposure, dermal indoor exposure, etc. (guidelines 875.1100 through 875.1500). EPA has made no further revisions to any other proposals on this series of data requirements.

The final rule conditionally requires the data to be submitted when the use of the biochemical pesticide could result in exposure levels that might exceed those historically encountered, and if so, other additional information would be necessary (e.g., directions for use, application rates, or other exposure information) to determine potential risks.

Thus, in general, when the use of any biochemical pesticide can be expected to exceed historical exposure to humans or the environment, the Agency would require exposure information to assure minimal risk associated with that use. Although it is true that insect repellents are typically applied at levels that can be expected to exceed those historically encountered, many other pesticide use patterns may also result in exposure levels exceeding these historically encountered use patterns. Again, these data requirements are not limited to insect repellents.

6. *Product use information data requirement—summary and Response to comments.* The Agency proposed to require product use information (guideline 875.1700). EPA received comments that this information was not necessary because this same basic use information is available as part of the registration or experimental use permit application. EPA agrees with the commenters and has removed this requirement from the final rule.

7. *Mutagenicity data requirements—summary of comments* . EPA proposed to provide more guidance for mutagenicity testing by specifying what kinds of studies would be required at Tier I and Tier II. This information was previously described in the 1982 published Subdivision M guidelines that indicated that Tier I would be *in*

vitro testing and Tier II would be *in vivo* testing. EPA proposed to add two of the three *in vitro* studies to the table for mutagenicity Tier I testing, and the two *in vivo* studies were added to the data table for mutagenicity Tier II testing. Three comments were received. One commenter mistakenly thought we had an *in vivo* study at Tier I but did urge us to use non-animal methods at Tier I referencing an EPA tiered testing proposal by Dearfield, et al. (Ref. 1). Another commenter recommended that we include an *in vitro* chromosome aberration test at Tier I to better address chromosomal endpoints. The third commenter was concerned that an *in vivo* chromosomal aberration or clastogenicity study was moved to Tier II and recommended an *in vivo* test be included at Tier I.

Summary of response to comments. Although the commenters were not totally accurate about the presence of *in vivo* chromosome studies being at the Tier I level (they were not actually at Tier I in the original nor the proposed guidelines, although the original table was not definitive by itself), the Agency believes the recommendation of the second commenter will address all these concerns. Therefore, the *in vitro* mammalian chromosome aberration study, guideline 870.5375, will be included in the Tier I Mutagenicity Testing battery of acceptable tests to better address chromosomal endpoints. This will correspond better to the mutagenicity testing description for the conventional pesticide data requirements, and will provide a more complete Tier I assessment.

8. *Primary eye, dermal and skin sensitization data requirements—summary of comments*. The Agency proposed to require both TGAI and EP testing, for EPs and TGAI and MP testing for MPs. The prior rule did not require TGAI testing. One commenter did not understand why the Agency expanded the data requirements to add the TGAI as the requisite test material.

Summary of response to comments. The Agency indicated in the preamble of the proposed rule that inert ingredients as well as active ingredients could cause adverse effects not necessarily noted by TGAI alone. Therefore, testing on both TGAI and EP or MP is necessary to determine the safety of the pesticide for these endpoints. As a result, EPA is finalizing both TGAI and EP or MP testing.

9. *Limit testing—summary and response to comments*. The Agency did not propose any revisions on limit testing for avian acute toxicity testing, but one commenter indicated support for the new methods in reducing the number of test animals used for conducting the study. The Agency minimizes testing as much as possible and often encourages the use of maximum hazard testing using only the high dose level, anticipating that no significant effects will be seen.

10. *Sediment/soil adsorption/desorption data—summary of comments*. EPA proposed a revision in the sediment toxicity data requirement in Tier I from ''not required'' to ''conditionally required'' for greenhouse use. The Agency also revised the test note. One commenter requested that the Agency clarify why these data would be required for greenhouse use.

Summary of response to comments. The Agency indicated the data may be conditionally required for greenhouse use to determine if the parent compound remains bound while grown in greenhouse conditions and is available for uptake in the plant. Likewise, it may need to be determined how rapidly the parent degrades in the growing medium, into what forms it may degrade, and whether the degradates are bound in the growing medium or taken up by the plant.

VI. Microbial Pesticides Data Requirements (Subpart V)

A. Definition of Microbial Pesticide

1. *Summary of proposal*. The Agency proposed to revise the definition of a microbial pesticide as follows:

Microbial pesticide means a microorganism intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, that:

i. Is a eucaryotic microorganism including, but not limited to, protozoa, algae, and fungi.

ii. Is a procaryotic microorganism, including, but not limited to bacteria.

iii. Is an autonomous replicating microscopic element, including, but not limited to, viruses.

EPA proposed this revision to 40 CFR 158.65 to better conform to the description of the class of non-exempt biological control agents in 152.20(a)(3), and to use a structure for defining microbial pesticide similar to that at 40 CFR 172.43. EPA explained that the proposed revisions are not intended to change, and in EPA's view does not change, the scope of the previous regulatory definitions and descriptions of microbial pesticides at §§ 158.65, 152.20(a)(3), or § 172.43. EPA also proposed changes to § 172.43 so that the definition would conform to the newly proposed definition of microbial pesticide, but did not intend to change the scope of that provision. These revisions are intended to include all microorganisms as microbial pesticides based on the currently accepted taxonomic nomenclature as of the date of publication of this rule.

EPA also proposed to refine the current regulatory text relating to the need to separately register new species or isolates and to separate that provision from the definition section to avoid confusion on the definition of microbial pesticide.

In the preamble to the proposed rule, EPA noted that microorganisms are known to produce many chemical pesticidal substances. These pesticidal substances, when distributed or sold independently of the microorganism, are considered to be biochemical pesticides, conventional chemical pesticides, or antimicrobial pesticides, depending on the mode of action and the use. The microorganism would then usually be considered part of the manufacturing process. For example, streptomycin, an antibiotic produced by a bacterium, *Streptomyces griseus*, is registered as a conventional chemical fungicide.

See Unit VIII.A. of the preamble to the proposed rule (71 FR 12072, March 8, 2006) for a more complete discussion of the changes proposed for the definition of microbial pesticide.

2. *Summary of comments*. The Agency received a total of five comments on the proposed definition of a microbial pesticide. Some commenters expressed concerns that the microbial pesticide definition might not adequately describe all microbial pesticides. One recommended including bacteriophages. Another commenter asked if nematodes (which may have symbiotic microorganisms living in them) are covered by the definition. Several commenters generally agreed with the provision in EPA's prior definition that specifies that each new isolate of a microorganism should be evaluated as a new strain. However, one of these commenters was concerned that, particularly for baculoviruses, there may be a few cases in which some microorganisms could be evaluated at a family or genus level for some test data requirements such as for human health toxicity/pathogenicity testing, even if each microorganism is a different strain, while in other cases an isolate might not ''always meet the definition for a strain.'' The commenter is concerned that maintaining the provision from the prior definition might require more testing than is necessary.

3. *Summary of response to comments*. To address the concerns about the adequacy of the microbial pesticide definition, the Agency added the

procaryotic class Archaea as an example to the class Bacteria since this is another division of procaryotes that is on the level of bacteria, at least according to some taxonomic schemes. Although this does not change the scope of the definition as implemented and proposed by EPA, this will ensure that this part of the definition is much clearer by explicitly including that entire group of microscopic living organisms. EPA also considered including bacteriophages in the ''autonomous replicating'' class under the revised microbial definition, which, as proposed, only included ''viruses'' as an example. However, EPA decided that it would not be appropriate from a taxonomic viewpoint. Bacteriophages are viruses that infect prokaryotes. Including a subcategory of viruses, i.e. the bacteriophages, as well as ''viruses'' would tend to confuse the language in the regulation and adds nothing to the scope of the definition. In addition, the original language in the preamble to the proposed rule was not quite accurate in describing viruses, i.e. ''the autonomous replicating language is intended to exclude pesticide components of microscopic cells that are not able to replicate as separate entities, such as genetic constructs.'' Because viruses replicate utilizing some components of a host cell, the ''autonomous replicating'' language would not accurately capture the relevant biology or the viruses we have registered. Therefore, EPA is changing the phrase ''autonomous replicating microscopic element'' to ''parasitically replicating microscopic element'' in part 3 of the definition. Under this definition, genetic constructs inserted intentionally into a microbial agent to provide pesticidal traits are not included because they do not parasitically replicate; however, the genetically altered microbial agent itself would be regulated as a microbial pesticide. We also changed the language in the definition from ''microorganism'' to ''microbial agent.'' This better agrees with the language in 40 CFR 152.20(a) which exempts ''Certain biological control agents'' from regulation under FIFRA.

In response to the comment concerning nematodes, EPA will offer some general guidance on nematodes here. Nematodes have been identified as a macroscopic biocontrol organism that is exempt from regulation in accordance with § 152.20(a) on the basis that another Federal regulatory agency is adequately regulating them. However, EPA is aware that the insecticidal activity of some commercially marketed nematodes is due to insecticidal microorganisms that live in a symbiotic relationship inside the nematode gut, (e.g., *Xenorhabdus* spp. and *Photorhabdus* spp., entomopathogenic bacteria associated with nematodes of the families Steinernematidae and Heterorhabditidae). In response to previous inquiries from researchers working with these biocontrol organisms, EPA determined that these symbiotic bacteria are considered a part of the mode of action of the exempt nematodes and are therefore covered by the exemption in § 152.20. Many exempt biocontrol organisms have naturally-occurring microbial flora living within them. However, if these bacteria were isolated, grown separately, and reinoculated into the nematodes as a delivery system, EPA has determined that the exemption does not apply and, thus, a registration would be required (USEPA, 1990)(Ref. 2). Likewise, genetic engineering of the symbiotic insecticidal microorganisms would also require them to be regulated as microbial pesticides.

EPA carefully considered the comment raising the issue of whether an isolate occasionally could be evaluated to satisfy a subset of data requirements at a higher taxonomic level than strain level and whether an isolate might sometimes be included as part of a very similar strain. EPA believes the proposed microbial pesticide definition applicability provision is sufficiently flexible to ensure adequate consideration and data on new isolates, while allowing use of existing data to support registration if similar to an existing strain that is already registered. The wording of the provision relating to applicability of the microbial data requirements reads, ''each new isolate of a microbial pesticide is treated as a new strain and must be registered independently of any similar registered microbial pesticide strain and supported by data required in this subpart.'' This wording does not preclude the possibility of using data from another isolate to support the assessment if it can be shown that the two isolates are sufficiently closely related. In this way it ensures that each isolate will be independently considered for registration purposes. The differences in taxonomy between different microorganism classifications, particularly for baculoviruses, would make any attempt to further clarify this provision very complex and potentially confusing as the systematic nomenclature of these organisms change over time. The Agency intends to use its best scientific judgment in each instance to determine if one isolate is sufficiently closely related to another isolate to allow sharing of data or waiving of data requirements.

B. Amendment of Parts 172 and 152

The definition of a microbial pesticide has been revised as follows:

(1) ''Microbial agent'' replaces ''microorganism;''

(2) ''Eubacteria and Archaebacteria'' replaces bacteria; and lastly,

(3) ''parasitically'' replaces ''autonomous''.

These revisions were incorporated and were also replaced in other sections of 40 CFR. To better coordinate the regulations, EPA proposed to replace the definition for a microbial pesticide at 40 CFR 172.43 with an updated definition. In addition, the Agency has also identified § 152.403 as another location in 40 CFR where the definition of a microbial pesticide is cross-referenced. Accordingly, this provision also needs to be corrected to reference the new § 158.2000 and § 158.2100. EPA has also proposed to delete § 158.65 in the proposed rule for conventional pesticides. EPA received no comments on this change to parts 152 and 172.

C. Individual Issues Submitted on Microbial Pesticides Data Requirements

A number of issues were identified that were focused on the guidelines, i.e., number of applications, maximum dosing of pesticides during testing, etc. These issues are outside the scope of this rule and EPA will consider them in the context of guideline development.

The following issues were identified for specific data requirements for microbial pesticides. The Agency responds to these comments in this preamble. When appropriate, the Agency has revised the regulatory text.

1. *EP versus TGAI testing for data requirements—summary of comments.* EPA proposed to require testing on TGAI for various data requirements instead of MP, or TEP or vice versa.

Summary of response to comments. One commenter indicated that the EP should be tested instead of the TGAI for physical and chemical properties data requirements. The Agency agrees with the commenter and understands that for meeting the chemical and physical properties data requirements, some product analyses should be done on the product proposed for registration, either an MP or EP. However, some product analyses should be done with TGAI. EPA proposed no change to the test substance currently being required. Rather, EPA simply broke out the various tests that make up the body of the product analyses data. Therefore, the data being required are on TGAI or

EP just as often as before, but with the revised table, it is more clear when TGAI or TGAI and MP/EP data are required for each specific test is listed (odor, color, etc.).

2. *Analytical methods data requirement—summary of comments.* EPA proposed to move the data requirement for analytical methods from the Product Analysis Data Table to the Residue Data Table. One commenter indicated that the analytical method should be required as a chemical and physical properties data requirement.

Summary of response to comments. The Agency is continuing to require these data but believes it more appropriate to require the data as a residue chemistry data requirement where it primarily would be needed if the microorganism could produce residues of concern, such as toxins. For general analysis of less problematic microorganisms, the new requirement for deposition of a sample to a culture collection where it would be available for use with standard microbial analytical comparison methods is sufficient to allow post registration analysis. This is to ensure that the product being registered is what was tested and evaluated.

3. *Quality assurance/quality control issue—summary of comments.* EPA did not propose a revision in the manufacturing process data requirement. One commenter indicated that a detailed description of quality assurance/quality control (QA/QC) program as part of the manufacturing/production process should be clearly specified as a data requirement.

Summary of response to comments. The Agency agrees with the commenter that the QA/QC program is especially critical for microbial agents. The existing regulations address these concerns by requiring confirmation that QA/QC is an essential part of the manufacturing process description as well as the discussion on formation of unintentional products and impurities.

4. *Acute injection toxicity/pathogenicity data requirement—summary of comments.* EPA proposed to eliminate the intracerebral administration and rely on the intravenous or intraperitoneal administration for the acute injection toxicity/pathogenicity study. One commenter agreed that elimination of the intracerebral injection assay was reasonable, but indicated it was unclear why the data were not required to support registration of viruses. Another commenter indicated that the pathogenicity/toxicity study via the intravenous (i.v.) or subcutaneous (s.c.) route should not be required for viruses.

Summary of response to comments. The requirement for the intracerebral injection assay is eliminated since it is difficult to accomplish and has questionable utility for detecting effects given the high likelihood of adverse effects from the method itself.

The Agency is not requiring pathogenicity/toxicity data for viral agents based on the difficulty of establishing the clearance endpoint for viruses. In these tests, the individual organ macerates must be tested for infectivity by a bioassay in the target pest. The Agency finds that the results from the cell culture assays are more sensitive and present a greater potential for the virus to express infectivity and cytopathic effects. The final rule is the same as the proposed rule for this data requirement.

5. *Hypersensitivity incidents data requirement—summary of comments.* EPA proposed to revise the hypersensitive incident data requirement from ''conditionally required'' (CR) to ''required'' (R) to better describe the occurrence and when it is actually required. One commenter requested more guidance on when to report hypersensitivity incidents to the Agency, and indicated that the elimination of the sensitization study could not be supported.

Summary of response to comments. For clarification, EPA did not require a ''sensitization'' study for microbial pesticides in either the original or the proposed rule. The original rule required a hypersensitivity study and reporting of hypersensitivity incidents. The proposed rule proposed to remove the requirement for hypersensitivity studies but continue the requirement for reporting of data for hypersensitivity incidents. The reference was changed from CR to R for the hypersensitivity reporting to better indicate that the data are required with no exceptions for all use patterns, if any hypersensitivity incidents occur. The Agency expects that many microbial pesticides may be respiratory sensitizers, although there are no consistently reliable laboratory tests available for this endpoint. Therefore, in general, the Agency requires protective equipment to lessen exposure to microbial agents for applicators with a high likelihood of repeated exposure. The requirement for reporting of human hypersensitivity incidents is to track microorganisms that may require more protective measures than those generally followed. The Agency agrees with the comment that more guidance on when to report would be helpful and is adding to the footnote the following language from the ''when required'' section of the 1982 Subdivision M Guideline 152.37 referenced in the original data requirements for Hypersensitivity Incidents and as slightly revised in the 1989 Guidelines (152A-15): ''3. Hypersensitivity incidents, including immediate-type and delayed-type reactions, of humans or domestic animals that occur during the testing or production of the TGAI, MP, or EP, or are otherwise known to the applicant, must be reported if they occur.'' Additional guidance is provided by 40 CFR 152.50(f)(3), which specifies that an applicant must include in a registration application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on humans or the environment.

6. *Mutagenicity data requirements—summary of comments.* EPA proposed to no longer require mutagenicity data on the whole microorganism. One commenter disagreed with the Agency, and indicated that mutagenicity data should be required on the whole organism. The commenter indicated that, especially for a new microorganism, basic genotoxicity studies (*in vitro*) might indicate the presence of metabolites/toxins with mutagenic properties that otherwise would not have been detected. Thus, basic studies should be kept on the list, at least as conditionally required. This same commenter indicated a concern for immunocompromised people and the possible production of antibiotic substances or the spread of antibiotic resistance to human or animal pathogens that could occur.

Summary of response to comments. The Agency's experience with standard mutagenicity testing shows that it is not appropriate for whole microorganisms or often even for slurries. These mixtures often interfere with the results from the tests. If toxins that may be mutagenic are identified as part of the Tier I testing and/or are known to be present in taxonomically related microorganisms, they can be tested as part of the acute testing requirements at Tier II. The Agency's approach is to require testing that identifies whether known problematic toxins are present in that isolate. The significant part of a microbial assessment comes from the taxonomic description of the organism that is used to search the literature to identify any problematic toxins that warrant individual assessment.

EPA evaluates potential effects on immunocompromised people as part of the assessment process of a microbial pesticide, considering its relationship to known human pathogens, the test data, and the potential exposure from its use.

EPA agrees most naturally-occurring microorganisms have evolved some sort of antibiotic mechanisms to help them survive in the presence of other microorganisms. However, rarely would significant levels of an antibiotic be produced from uses of microbial pesticides that might produce a disease problem. If a microorganism that could produce significant levels of a clinically important antibiotic was proposed for a pesticidal use that might affect medicinal uses of that antibiotic, it would be handled on a case-by-case basis by knowledgeable EPA scientists. After careful consideration, the mutagenicity data requirements remain the same in the final rule as in the proposed rule.

7. *Infectivity/pathogenicity data requirement—summary of comments*. EPA proposed to conditionally require infectivity/pathogencity data as a Tier III data requirement. One commenter was opposed to the new data requirement for infectivity/pathogenicity.

Summary of response to comments. The Agency understands the concerns of conditionally requiring higher tiers of mammalian testing. EPA believes, however, that there may be instances in which a microbial pesticide is intended for control of a mammalian pest, and such tests may be needed to assure the safety for non-target mammalian species. This same commenter also strongly opposed the use of primates for this testing and oncogencity/carcinogenicity testing. The Agency doubts a registrant would go to the extremes of performing a primate study to try to support registration of a mammalian pathogen. The data requirements in the final rule remain the same as in the proposed rule.

8. *TEP testing for non-target ecological effects*. EPA proposed some revisions to provide the option for testing either the TEP or TGAI for non-target ecological effects. One commenter recommended TEP or EP testing for all products with potential aquatic or terrestrial non-target exposure.

Summary of response to comments: The Agency agrees with the commenter that EP testing should be required when significant non-target exposure is to be expected. Therefore, the Agency has added a new test note to require EP or TEP testing when the EP may contain other ingredients that may be toxic to non-target organisms. The Agency has added TEP to freshwater fish/pathogenicity and invertebrate/pathogenicity testing data requirements.

9. *Honeybee toxicity testing—summary of comments*. The Agency proposed one test note revision to the honeybee toxicity study for indoor use and Experimental Use Permits (EUPs). One commenter indicated the data requirement refers mainly to oral effects, and that the Agency should consider dermal/topical effects as well, suggesting it would improve harmonization with other data requirements, if the dermal/topical acute toxicity test was also included as an option.

Summary of response to comments. The data table does not specify the route of exposure for the honeybee toxicity testing. The route of exposure for this test is addressed in its OPPTS Microbial Pesticide Harmonized Test Guideline, 885.4380, which is available on the EPA's web site at *http://www.epa.gov/opptsfrs/home/guidelin.htm* and which is referenced in the data table. This guideline recommends using an oral dose if the microbial pesticide is expected to act by a dietary route of exposure or consists of particles of such a size that they might be carried back to the hive like pollen. However, we recognize that most honeybee oral dosing methods would likely also result in some dermal exposure. Furthermore, the guideline does not rule out using a conventional dermal/topical exposure as an option if the mode of action of the microbial pesticide indicates that it would be more appropriate.

10. *Environmental expression data requirements—summary of comments* . EPA did not propose to change when the Tier II environmental fate, i.e. expression, testing would be triggered by Tier I acute toxicity testing. However, one commenter indicated that the data requirements on environmental expression are very limited. The commenter recommended, to improve harmonization with the European Union (EU), that EPA should add substantial guidance to the test notes 9, 10, and 11 (or references to relevant literature) on what environmental fate data should be collected, presented, and submitted, in case a Tier II evaluation is required.

Response to comments: The guidance that the commenter recommends be added to the regulatory text is found in our guidelines, specifically guidelines 885.5200, 885.5300, and 85.5400, which are referenced in the data tables. Historically, EPA has provided detailed guidance on a case-by-case basis. The EU and the US have agreed to use the same microbial pesticide testing guidelines, so these would be the best place to address this concern. The EPA will continue to address EU harmonization through the OECD Biopesticides Steering Group.

11. *Reduction in number of test animals used for testing—summary of comments*. EPA did not propose any revisions to the test guidelines within this proposed rule. Two commenters supported the development of new methods to reduce the number of animals used for pesticide testing while maintaining the diversity of test species.

Summary of response to comments. The revision of the guidelines is a separate activity. The OPPTS Microbial Test Guidelines already recommends a single high dose for the initial test using a minimal number of test animals and provides for enough replicates with sufficient statistical power. Specifically, high dose tests (basically high dose screening tests using a low number of test animals and replicates) by their very nature provide sufficient statistical power to avoid type II (beta) errors.

12. *Non-target organisms and environmental fate testing*. Both the original and the proposed testing for non-target effects and environmental fate are organized into tiers, with the effects testing at the Tier I level and the environmental exposure testing at the Tier II level. One commenter requested the Agency conduct the fate and exposure studies at Tier I and put the non-target studies using living test organisms at Tier II and higher. The commenter suggested limiting Tier I data requirements to strictly non-vertebrate studies, e.g., environmental expression studies, and substituting some *in vitro* studies such as a fish egg and a protozoan toxicity study for *in vivo* fish studies.

Summary of response to comments. The Agency does not believe this suggestion would allow an adequate assessment to be done. The basis for the microbial pesticide ecological risk assessment is to first determine if there are any significant adverse effects with a maximum hazard approach. The maximum hazard approach to testing uses one dosing group of animals (mice, rats, birds, etc) tested at a very high dosage of the test substance on the presumption that no adverse effects will be seen. If no significant adverse effects are seen at the maximum dosage, exposure data are not required. The Agency minimizes testing as much as possible and often encourages the use of maximum hazard testing when no significant effects are expected to be seen at that level. This is especially pertinent to microbial pesticides which rarely show any significant effects in the high dose and it has dramatically reduced the number of test animals used and also reduced the cost of the testing.

Definitive environmental expression studies are very difficult to perform for naturally-occurring microorganisms that can increase in numbers in the

environment under varying conditions, in contrast to chemical pesticides for which environment fate studies are designed to determine only how fast they degrade and/or are transported. An environmental expression study on a microorganism rarely, if ever, would be sufficiently conclusive to allow bypassing the easier-to-perform *in vivo* effects studies. However, a careful preregistration analysis of the proposed uses and known environmental characteristics of the specific microorganism usually allows for some data waivers of the Tier I studies to be granted. The proposal for substituting the two *in vitro* studies to replace a study on fish is worth further study as an alternative to the standard fish study, but it is not clear at this time if it would accurately detect the potential for microbial infectivity and pathogenicity.

13. *Addition of other test species—summary of comments.* One commenter suggested adding testing of freshwater algae, terrestrial micro-organisms, and the active micro-organisms in sewage treatment plants, as these may be exposed as well to general use, biochemical, or microbial pesticides.

Summary of response to comments. Current knowledge indicates that the inherent variability in physical and biological environments, the adaptability of microbes, and redundant degradation pathways in microbial and mesofaunal communities, leads to no significant or lasting impact on ecosystems from introduction of pesticidal microbes even where changes to these populations can be meaningfully tracked. (Refs. 3 and 4). Moreover, microbial ecosystems are highly variable. Any transitory, limited, effects from the introduction of a typical microbial pesticide into the environment would be very difficult to detect and analyze. The active microorganisms in sewage treatment plants are also part of a complex specialized microbial community that is very competitive and is also very unlikely to be influenced by any one given microbial pesticide.

VII. Experimental Use Permits

In promulgating its final rule on conventional pesticides, EPA segregated the Experimental Use Permit (EUP) data requirements into a separate subpart C. This was done in response to comments suggesting this change for clarity and to avoid confusion about the purpose of the brackets. For consistency and ease of use, EPA has adopted this new format for biochemical and microbial pesticides. Accordingly, the brackets have been removed from the product chemistry, residue, toxicology, non-target organism, and environmental fate data tables.

The new data requirements for experimental use permits are listed in § 158.2080 for biochemical pesticides and § 158.2170 for microbial pesticides.

VIII. Implementation

After the effective date, the data requirements in this final rule will apply to all new registrations of biochemical pesticides and microbial pesticides. The Agency does not intend to apply these requirements retroactively to all existing pesticide registrations but the Agency may find it necessary to call in some data on certain existing registrations, as warranted by emerging risks of concern on particular pesticides or as a result of possible programmatic changes and priorities on existing pesticides.

FIFRA sec. 3(c)(2) provides EPA broad authority, before and after registration, to require scientific testing and submission of the resulting data to the Agency by registrants and applicants of pesticide products. Although the data requirements in part 158 are imposed primarily as a part of initial registration, EPA is authorized under FIFRA sec. 3(c)(2)(B) to require a registrant to develop and submit additional data to maintain a registration. This post-registration data call-in authority recognizes that the scientific underpinnings of risk assessment change, and is another means by which EPA may keep data for use in risk assessment current with evolving science.

EPA will consider as part of its review of a pending application whether and how to apply these updated data requirements. EPA expects that few changes will be needed, as these updated requirements reflect current practice.

IX. References

The following is a listing of the documents that are specifically referenced in this final rule. These documents and other supporting materials are included in the docket established for this rulemaking under docket ID No. EPA-HQ-OPP-2004-0415 at *http://www.regulations.gov*.

1. Dearfield, K.L., Cimino, M.C., McCarroll, N.E., et al. ''Genotoxicity risk assessment: a proposed classification strategy.'' *Mutation Research* 521, 121-135 (2002).

2. December 3, 1990 EPA memo: Schneider to Hutton.

3. Gagliardi, J.V., Buyer, J.S. Angle, J.S. and Russek-Cohen, E. 2001a. Structural and functional analysis of whole-soil microbial communities for risk and efficacy testing following microbial inoculation of wheat roots in diverse soils. Soil Biol. Biochem. 33:25-40.

4. Gagliardi J.V., Angle J.S., Germida J.J., Wyndham R.C., Chanway C.P., Watson R.J., Greer C.W., McIntyre T, Yu H.H., Levin M.A., Russek-Cohen E, Rosolen S, Nairn J, Seib A, Martin-Heller T, Wisse G. 2001b. Intact soil-core microcosms compared with multi-site field releases for prerelease testing of microbes in diverse soils and climates. *Can J Microbiol.* 47(3):237-52.

5. U.S. EPA, 2006. ''Economic Analysis of the Final Data Requirements For Biochemical And Microbial Pesticides Rule.'' FEAD/OPP/U.S. EPA, Washington, D.C.

6. U.S. EPA, 2002. ''Supporting Statement for an Information Collection Request: Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients.'' OMB Control No. 2070-0024, EPA ICR No. 0597. OPP/U.S. EPA, Washington, D.C.

7. U.S. EPA, 2002. ''Supporting Statement for an Information Collection Request: Application for New or Amended Pesticide Registration.'' OMB Control No. 2070-0060, EPA ICR No. 0277. OPP/U.S. EPA, Washington, D.C.

8. U.S. EPA, 2001. ''Supporting Statement for an Information Collection Request:'' Data Generation for Reregistration; Phase 4 and 5 Reregistration.'' OMB Control No. 2070-0107, EPA ICR No. 1504. OPP/U.S. EPA, Washington, D.C.

9. U.S. EPA, 2001. ''Supporting Statement for an Information Collection Request: Data Call-Ins for the Special Review and Registration Review Programs.'' OMB Control No. 2070-0057, EPA ICR No. 0057. OPP/U.S. EPA, Washington, D.C.

10. U.S. EPA, 2004. ''Supporting Statement for an Information Collection Request: Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting.'' OMB Control No. 2070-0142, EPA ICR No. 1693, Washington, D.C.

X. FIFRA Review Requirements

In accordance with FIFRA sec. 25(a), the Agency submitted a draft of this final rule to the FIFRA Scientific Advisory Panel (SAP), the Secretary of Agriculture, and the Committee on Agriculture in the House of Representatives, and the Committee on Agriculture, Nutrition, and Forestry in the United States Senate.

The FIFRA SAP waived its review of this final rule because the significant scientific issues involved have already been reviewed by the SAP and additional review is unnecessary.

XI. Statutory and Executive Order Review

A. Regulatory Planning and Review

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this action is a significant regulatory action because it might raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted this action to OMB for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action as required by sec. 6(a)(3)(E) of the Executive Order.

In addition, EPA has prepared an analysis of the potential costs and benefits associated with this action, entitled *Economic Analysis of the Final Data Requirements For Biochemical And Microbial Pesticides Rule (Economic Analysis).* (Ref. 4). A copy of this analysis is available in the docket for this rule and is briefly summarized here.

For the proposed rule, EPA estimated that the total annual impact to the pesticide industry is a regulatory compliance cost reduction of $3.04 million per year, with an estimated average cost reduction of $60,000 per firm, per year. During the public comment period for the proposed rule, no comments were received on the economic analysis. The majority of the comments on the proposed rule focused on definitional issues; none of the clarifications made in this final rule affect the Agency's estimate on the total annual impact to the pesticide industry. Accordingly, no substantive changes have been made to the Economic Analysis for this rulemaking.

As such, the likely impact of this final rule on businesses overall is expected to be mostly beneficial. EPA believes that the final rule would have no effect on the availability of pesticides to users. On balance, the Agency believes that cost savings resulting from the final changes to the data requirements presented in this final rule can be realized without compromising the protection of human health and the environment.

B. Paperwork Reduction Act (PRA)

This final rule does not contain any new information collection requirements that require additional approval by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq. Under the PRA, 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, or is otherwise required to submit the specific information by a statute. The OMB control numbers for EPA's regulations codified in Title 40 of the CFR, after appearing in the preamble of the final rule, are further displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in a list at 40 CFR 9.1.

Under the PRA, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to: review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust 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 (i.e., the paperwork collection activities) related to the submission of data necessary to register a pesticide product are already approved by OMB under several existing information collection requests (ICR). Specifically, the activities that would generate a paperwork burden under this rule are covered by the following ICRs:

- The activities associated with the establishment of a tolerance are currently approved under OMB Control No. 2070–0024 (EPA ICR No. 0597) (Ref. 5).
- The activities associated with the application for a new or amended registration of a pesticide are currently approved under OMB Control No. 2070–0060 (EPA ICR No. 0277) (Ref. 6).
- The activities associated with the generation of data for reregistration are currently approved under OMB Control No. 2070–0107 (EPA ICR No. 1504) (Ref. 7).
- The activities associated with the generation of data for special review or registration review are currently approved under OMB Control No. 2070–0057 (EPA ICR No. 0922) (Ref. 8).
- The activities associated with notification of genetically modified microbial pesticides are currently approved under OMB Control No. 2070–0142 (EPA ICR No. 1693) (Ref. 9).

These existing ICRs cover the paperwork activities contained in this rule because these activities already occur as part of existing program activities. These program activities are an integral part of the Agency pesticide program, and the corresponding ICRs are regularly renewed as required under the PRA, such that these OMB Control Nos. are maintained valid.

Based on these existing approvals, the Agency estimates that the total average annual public reporting burden currently approved by OMB for these various activities ranges from 8 hours to approximately 3,000 hours per respondent, depending on the activity and other factors surrounding the particular pesticide product. Additional information about this estimate is provided in the Economic Analysis for this rulemaking.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the *Regulatory Flexibility Act* (RFA), 5 U.S.C. 601 et seq., the Agency hereby certifies that this rule will not have a significant adverse economic impact on a substantial number of small entities. This determination is based on the Agency's Economic Analysis performed for this rulemaking, which is summarized in Unit IX.A. above, and a copy of which is available in the docket for this rulemaking. The following is a brief summary of the factual basis for this certification.

Under the RFA, small entities include small businesses, small not-for-profit organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined in accordance with the RFA as: (1) A small business as defined by the Small Business Administration's (SBA) regulations 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.

Based on the industry profile that EPA prepared using historical pesticide registration data as part of the Economic Analysis prepared for this rulemaking, EPA has determined that this rule is not expected to impact any small not-for-profit organizations or small governmental jurisdictions. The

historical data indicates that these types of entities do not engage in the activities covered by this rulemaking. As such, the small entity impacts analysis evaluates potentially impacted businesses that could be considered small businesses as defined by the Small Business Administration, which uses the maximum number of employees or sales for businesses in each industry sector, as that sector is defined by NAICS. For example, entities defined as Pesticide and Other Agricultural Chemical Manufacturing (325320) are considered to be a small business if they employ 500 or fewer people.

EPA then used historical data to estimate the impacts of the rule on these small businesses. Of 51 firms with biochemical or microbial registration actions between 1997 to 2004, financial data for determining company size was available for 40 firms, with 23 of those firms classified as small businesses. According to the analysis, all of these small entities would realize a reduction in costs based on the rule changes compared to the current part 158 data requirements. Given these estimated impacts on small businesses, EPA concluded that the revisions in this rule may benefit and would not likely have a significant adverse economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4), EPA has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. As described in Unit XI.A., the total annual impact to the pesticide industry is estimated to be a regulatory compliance cost reduction of about $3.04 million per year.

In addition, since State, local, and tribal governments are rarely pesticide applicants or registrants, the final rule is not expected to significantly or uniquely affect small governments. Accordingly, this action is not subject to the requirements of sections 202 and 205 of UMRA.

E. Federalism Implications

Pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this rule does not have ''federalism implications,'' because it would 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 the Order. Because instances in which a State is a registrant are extremely rare, this final rule may seldom affect a State government. Thus, Executive Order 13132 does not apply to this rule.

F. Tribal Implications

As required by Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), EPA has determined that this final rule does not have tribal implications because it would not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in the Order. At present, no tribal governments hold, or have applied for, a pesticide registration. Thus, Executive Order 13175 does not apply to this rule.

G. Protection of Children

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 final rule because this action is not designated as an ''economically significant'' regulatory action as defined by Executive Order 12866 (see Unit XI.A.). Further, this rule does not establish an environmental standard that is intended to have a negatively disproportionate effect on children. To the contrary, this action would provide added protection for children from pesticide risk. The requirements in this rule are intended to address risks that, if not addressed, could have a disproportionate negative impact on children. EPA will use the data and information obtained by this rule to carry out its mandate under FFDCA to give special attention to the risks of pesticides to sensitive subpopulations, especially infants and children.

H. Energy Implications

This rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because it is not designated as an ''economically significant'' regulatory action under Executive Order 12866 (see Unit XI.A.), nor is it likely to have any significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), (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 impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, etc.) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This regulation proposes the types of data to be required to support a biochemical or microbial pesticide registration but does not propose to require specific methods or standards to generate those data. Therefore, this regulation does not impose any technical standards that would require Agency consideration of voluntary consensus standards. EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the performance criteria specified. The Agency invited comment on its conclusion regarding the applicability of voluntary consensus standards to this rulemaking effort and did not receive any comments on this point.

J. Environmental Justice

This rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency is not required to and has not considered environmental justice-related issues. Although not directly impacting environmental justice-related concerns, the Agency believes that the requirements in this rule will assist EPA and others in assessing potential risks associated with exposures to biochemical and microbial pesticides.

XII. Congressional Review Act (CRA)

The Congressional Review Act, 5 U.S.C. 801 et seq., 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 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 the 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 Part 158

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

Dated: October 10, 2007.

Stephen L. Johnson,

Administrator.

■ Therefore, Title 40, chapter I, part 158 is amended as follows:

■ 1. The authority citation for part 158 continues to read as follows:

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 346a.

■ 2. By adding subparts U and V to part 158 to read as follows:

Subpart U—Biochemical Pesticides

Sec.

158.2000 Biochemical pesticides definition and applicability.
158.2010 Biochemical pesticides data requirements.
158.2030 Biochemical pesticides product chemistry data requirements table.
158.2040 Biochemical pesticides residue data requirements table.
158.2050 Biochemical pesticides human health assessment data requirements table.
158.2060 Biochemical pesticides nontarget organisms and environmental fate data requirements table.
158.2070 Biochemical pesticides product performance data requirements.
158.2080 Experimental use permit data requirements - biochemical pesticides.
158.2081 Experimental use permit biochemical pesticides product chemistry data requirements table.
158.2082 Experimental use permit biochemical pesticides residue data requirements table.
158.2083 Experimental use permit biochemical pesticides human health assessment data requirements table.
158.2084 Experimental use permit biochemical pesticides nontarget organisms and environmental fate data requirements table.

Subpart V— Microbial Pesticides

Sec.

158.2100 Microbial pesticides definition and applicability.
158.2110 Microbial pesticides data requirements.
158.2120 Microbial pesticides product analysis data requirements table.
158.2130 Microbial pesticides residue data requirements table.
158.2140 Microbial pesticides toxicology data requirements table.
158.2150 Microbial pesticides nontarget organisms and environmental fate data requirements table.
158.2160 Microbial pesticides product performance data requirements.
158.2170 Experimental use permit data requirements-microbial pesticides.
158.2171 Experimental use permit microbial pesticides product analysis data requirements table.
158.2172 Experimental use permit microbial pesticides residue data requirements table.
158.2173 Experimental use permit microbial pesticides toxicology data requirements table.
158.2174 Experimental use permit microbial pesticides nontarget organisms and environmental fate data requirements table.

Subpart U—Biochemical Pesticides

§ 158.2000 Biochemical pesticides definition and applicability.

This subpart applies to all biochemical pesticides as defined in paragraphs (a), (b), and (c) of this section.

(a) *Definitions*. The following terms are defined for the purposes of subpart U of this part.

(1) A *biochemical pesticide* is a pesticide that:

(i) Is a naturally-occurring substance or structurally-similar and functionally identical to a naturally-occurring substance;

(ii) Has a history of exposure to humans and the environment demonstrating minimal toxicity, or in the case of a synthetically-derived biochemical pesticides, is equivalent to a naturally-occurring substance that has such a history; and

(iii) Has a non-toxic mode of action to the target pest(s).

(2) A *Pheromone* is a compound produced by a living organism or is a synthetically derived substance that is structurally similar and functionally identical to a naturally-occurring pheromone, which, alone or in combination with other such compounds, modifies the behavior of other individuals of the same species.

(i) An *Arthropod Pheromone* is a pheromone produced by a member of the taxonomic phylum Arthropoda.

(ii) A *Lepidopteran Pheromone* is an arthropod pheromone produced by a member of the insect order Lepidoptera.

(iii) A *Straight Chain Lepidopteran Pheromone* is a lepidopteran pheromone consisting of an unbranched aliphatic chain (between 9 and 18 carbons) ending in an alcohol, aldehyde, or acetate functional group and containing up to three double bonds in the aliphatic backbone.

(b) *Examples*. Biochemical pesticides include, but are not limited to:

(1) Semiochemicals (insect pheromones and kairomones),

(2) Natural plant and insect regulators,

(3) Naturally-occurring repellents and attractants, and

(4) Enzymes.

(c) *Applicability*. The Agency may review, on a case-by-case basis, naturally-occurring pesticides that do not clearly meet the definition of a biochemical pesticide in an effort to ensure, to the greatest extent possible, that only the minimum testing sufficient to make scientifically sound regulatory decisions would be conducted. The Agency will review applications for registration of naturally-occurring pesticides to determine whether to review the pesticide under this subpart U.

§ 158.2010 Biochemical pesticides data requirements.

(a) Sections 158.2030 through 158.2070 identify the data requirements that are required to support registration of biochemical pesticides. Sections 158.2080 through 158.2084 identify the data requirements that are required to support Experimental Use Permits (EUPs). Variations in the test conditions are identified within the test notes. Definitions that apply to all biochemical data requirements can be found in § 158.2000.

(b) Each data table includes ''use patterns'' under which the individual data are required, with variations including food and nonfood uses for terrestrial and aquatic applications, greenhouse, indoor, forestry, and residential outdoor applications under certain circumstances.

(c) The categories for each data requirement are ''R'', which stands for required, and ''CR'' which stands for conditionally required. Generally, ''R'' indicates that the data are more likely required than for those data requirements with ''CR.'' However, in each case, the regulatory text preceding the data table and the test notes following the data table must be used to determine whether the data requirement must be satisfied.

(d) Each table identifies the test substance that is required to be tested to satisfy the data requirement. Test substances may include: technical grade active ingredient (TGAI), manufacturing-use product (MP), end-use product (EP), typical end-use

product (TEP), residue of concern, and pure active ingredient (PAI) or all of the above (All). Commas between the test substances (i.e., TGAI, EP) indicate that data may be required on the TGAI or EP or both depending on the conditions set forth in the test note.

(e) The data requirements are organized into a tier-testing system with specified additional studies at higher tiers being required if warranted by adverse effects observed in lower tier studies. The lower tier studies are a subset of those required for conventional pesticides, and the studies overall are generally selected from those required for conventional pesticides.

(f) Two sets of guideline numbers are provided for some of the environmental fate data requirements. For ease of understanding, the current guidelines will be used as an interim measure until the new guidelines (in parentheses) are finalized.

§ 158.2030 Biochemical pesticides product chemistry data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the product chemistry data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of the section.

(2) Definitions in § 158.300 apply to data requirements in this section.

(b) *Use patterns.* Product chemistry data are required for all pesticide products and are not use specific.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above.

(d) *Table.* The following table shows the data requirements for biochemical pesticides product chemistry. The test notes are shown in paragraph (e) of this section.

TABLE—BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Identity and Composition					
880.1100	Product identity and composition	R	TGAI, MP	TGAI, EP	1, 2
880.1200	Description of starting materials, production and formulation process	R	TGAI, MP	TGAI, EP	2, 3
880.1400	Discussion of formation of impurities	R	TGAI and MP	TGAI and EP	4
Analysis and Certified Limits					
830.1700	Preliminary analysis	CR	TGAI and MP	TGAI and EP	5, 8
830.1750	Certified limits	R	MP	EP	6
830.1800	Enforcement analytical method	R	MP	EP	7
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	8
830.6303	Physical state	R	TGAI and MP	TGAI and EP	8
830.6304	Odor	R	TGAI	TGAI	8
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	8, 17
830.6315	Flammability	CR	MP	EP	9
830.6317	Storage stability	R	MP	EP	--
830.6319	Miscibility	CR	MP	EP	10
830.6320	Corrosion characteristics	R	MP	EP	--
830.7000	pH	CR	TGAI and MP	TGAI and EP	8, 11
830.7050	UV/Visible light absorption	R	TGAI	TGAI	--
830.7100	Viscosity	CR	MP	EP	12
830.7200	Melting point/melting range	CR	TGAI	TGAI	8, 13

TABLE—BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
830.7220	Boiling point/boiling range	CR	TGAI	TGAI	8, 14
830.7300	Density/relative density/bulk density	R	TGAI and MP	TGAI and EP	8, 18
830.7520	Particle size, fiber length, and diameter distribution	CR	TGAI	TGAI	8, 15
830.7550 830.7560 830.7570	Partition coefficient (n-Octanol /Water)	CR	TGAI	TGAI	16
830.7840	Water solubility	R	TGAI	TGAI	8
830.7950	Vapor pressure	R	TGAI	TGAI	8, 19

(e) *Test notes*. The following test notes are applicable to the data requirements for biochemical pesticides product chemistry and are referenced in the last column of the table in paragraph (d) of this section.

1. Data must be provided in accordance with § 158.320.
2. If the MP and EP are produced by an integrated formulation system (non-registered source), these data are also required on TGAI.
3. Data must be provided in accordance with §§ 158.325, 158.330, and § 158.335.
4. Data must be provided in accordance with § 158.340.
5. Data must be provided in accordance with § 158.345. Also, required to support the registration of each manufacturing-use product (including registered TGAIs) and end-use products produced by an integrated formulation system. Data on other end-use products would be required on a case-by-case basis.
6. Data must be provided in accordance with § 158.350.
7. Data must be provided in accordance with § 158.355.
8. If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI. EP testing may also be appropriate.
9. Required if the product contains combustible liquids.
10. Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.
11. Required if the test substance is soluble or dispersible in water.
12. Required if the product is a liquid.
13. Required when the technical chemical is a solid at room temperature.
14. Required when the technical chemical is a liquid at room temperature.
15. Required for water insoluble test substances (>10^{-6}g/l) and fibrous test substances with diameter ≥0.1 μm.
16. Required for organic chemicals unless they dissociate in water or are partially or completely soluble in water.
17. Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.
18. True density or specific density are required for all test substances. Data on bulk density is required for MPs or EPs that are solid at room temperature.
19. Not required for salts.

§ 158.2040 Biochemical pesticides residue data requirements table.

(a) *General*. Sections 158.100 through 158.130 describe how to use this table to determine the biochemical pesticides residue data requirements for a particular pesticide product and the substance that needs to be tested. These data requirements apply to all biochemical pesticides, i.e. naturally occurring insect repellents and attractants, semiochemicals (e.g., insect pheromones), natural and plant growth regulators. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns*. (1) Data are required or conditionally required for all pesticides used in or on food and for residential outdoor uses where food crops are grown. Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use. Data are also conditionally required for aquatic nonfood use if there is direct application to water that could subsequently result in exposure to food.

(2) Data are conditionally required for nonfood uses if pesticide residues may occur in food or feed as a result of the use. Data requirements for these nonfood uses would be determined on a case-by-case basis. For example, most products used in or near kitchens require residue data for risk assessment purposes even though tolerances may not be necessary in all cases.

(c) *Key*. R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing end-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Data requirements table*. The following table shows the data requirements for biochemical pesticides residue. The test notes are shown in paragraph (e) of this section.

TABLE—BIOCHEMICAL RESIDUE DATA REQUIREMENTS FOR SPECIFIC USES

Guideline Number	Data Requirement	Use Patterns				Test Substance	Test Notes
		Terrestrial Food/Feed	Aquatic Food	Greenhouse Food	Indoor Food		
Supporting Information							
860.1100	Chemical identity	CR	CR	CR	CR	TGAI	1, 2, 4
860.1200	Directions for use	CR	CR	CR	CR	--	1, 3, 4
Nature of the Residue							
860.1300	Nature of the residue in plants	CR	CR	CR	CR	TGAI	1, 4, 5, 6
860.1300	Nature of the residue in livestock	CR	CR	CR	CR	TGAI or plant metabolite	1, 7, 8, 10, 13
860.1340	Residue analytical method	CR	CR	R	CR	Residue of concern	4, 9, 10
860.1360	Multiresidue method	CR	CR	R	CR	Residue of concern	10, 11
Magnitude of the Residue							
860.1400	Potable water	NR	CR	NR	NR	TGAI	1, 12
860.1400	Fish	NR	CR	NR	NR	TGAI	1, 13
860.1400	Irrigated crops	NR	CR	NR	NR	TGAI	1, 14
860.1460	Food handling	NR	NR	NR	CR	TGAI	1, 15
860.1480	Meat/milk/poultry/eggs	CR	CR	CR	CR	TGAI or plant metabolites	1, 7, 8, 10
860.1500	Crop field trials	CR	CR	CR	CR	TEP	1, 3, 4
860.1520	Processed food/feed	CR	CR	CR	CR	TEP	1, 16
860.1540	Anticipated residues	CR	CR	CR	CR	Residue of concern	1, 10, 17
860.1550	Proposed tolerances	CR	CR	CR	CR	--	1, 18
860.1560	Reasonable grounds in support of the petition	CR	CR	CR	CR	--	1, 10
860.1650	Submittal of analytical reference standards	CR	CR	CR	CR	TGAI and residue of concern	10, 19

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides product chemistry and are in the last column of the table contained in paragraph (d) of this section.

1. Residue chemistry data requirements apply to biochemical pesticide products when Tier II or Tier III toxicology data are required, as specified for biochemical agents in the biochemical human health assessment data requirements, §158.2050.

2. The same chemical identity data are required for biochemical product chemistry data requirements, §158.2030, with an emphasis on impurities.

3. Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

4. Required for residential outdoor uses on food crops if the corresponding agricultural use is not approved or the residential use is expected to produce higher residues based on the label directions .

5. Required unless it is an arthropod pheromone applied at a rate less than or equal to 150 grams active ingredient per acre.

6. Required for indoor uses where the pesticide is applied directly to food, in order to determine metabolites and/or degradates. Not required when only indirect contact with food would occur (e.g., crack and crevice treatments).

7. Required when a pesticide is to be applied directly to livestock, to livestock premises, to livestock drinking water, or to crops used for livestock feed.

8. If results from the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be required.

9. A residue analytical method suitable for enforcement of tolerances is required whenever a numeric tolerance (including temporary and time-limited tolerances) is proposed.

10. Required if indoor use could result in pesticide residues in or on food or feed.

11. Data are required to determine whether FDA/USDA multiresidue methodology would detect and identify the pesticides and any metabolites.

12. Data are required whenever a pesticide may be applied directly to water, unless it can be demonstrated that the treated water would not be available for human or livestock consumption.

13. Data on fish are required for all pesticides applied directly to water inhabited, or which will be inhabited by fish that may be caught or harvested for human consumption .

14. Data are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

15. Data are required whenever a pesticide may be used in food/feed handling establishments.

16. Data on the nature and level of residue in processed food/feed are required when detectible residues could potentially concentrate on processing thus requiring the establishment of a separate tolerance higher than that of the raw agricultural commodity.

17. Required when residues at the tolerance level may result in risk of concern. These data may include washing, cooking, processing, or degradation studies as well as market basket surveys for a more precise residue determination.

18. The proposed tolerance must reflect the maximum residue likely to occur in crops, in meat, milk, poultry, or eggs.

19. Required when a residue analytical method is required.

§ 158.2050 Biochemical pesticides human health assessment data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the biochemical human health assessment data requirements for a particular biochemical pesticide product.

(2) The data in this section are not required for straight chain lepidopteran pheromones when applied up to a maximum use rate of 150 grams active ingredient/acre/year.

(b) *Use patterns.* (1) Food use patterns, in general, include products classified under the following general uses: terrestrial food crop use; terrestrial feed crop use; aquatic food crop use; greenhouse food crop use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use; aquatic nonfood residential use; aquatic nonfood outdoor use; aquatic nonfood industrial use; greenhouse nonfood crop use; forestry use; residential outdoor use; residential indoor use; indoor food use; indoor nonfood use; indoor medical use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for biochemical pesticides human health assessment. The test notes are shown in paragraph (e) of this section.

TABLE—BIOCHEMICAL PESTICIDES HUMAN HEALTH ASSESSMENT DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes
		Food	Nonfood	MP	EP	
Tier I						
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	TGAI and MP	TGAI and EP	1
870.1200	Acute dermal toxicity	R	R	TGAI and MP	TGAI and EP	1, 2
870.1300	Acute inhalation toxicity - rat	R	R	TGAI and MP	TGAI and EP	3
870.2400	Primary eye irritation - rabbit	R	R	TGAI and MP	TGAI and EP	2
870.2500	Primary dermal irritation	R	R	TGAI and MP	TGAI and EP	1, 2
870.2600	Dermal sensitization	R	R	TGAI and MP	TGAI and EP	2, 4
none	Hypersensitivity incidents	R	R	All	All	5
Subchronic Testing						
870.3100	90-day oral (one species)	R	CR	TGAI	TGAI	6
870.3250	90-day dermal - rat	CR	CR	TGAI	TGAI	7
870.3465	90-day inhalation - rat	CR	CR	TGAI	TGAI	8
Developmental Toxicity						
870.3700	Prenatal developmental - rat preferably	R	CR	TGAI	TGAI	9
Mutagenicity Testing						

TABLE—BIOCHEMICAL PESTICIDES HUMAN HEALTH ASSESSMENT DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes
		Food	Nonfood	MP	EP	
870.5100	Bacterial reverse mutation test	R	CR	TGAI	TGAI	10
870.5300 870.5375	*In vitro* mammalian cell assay	R	CR	TGAI	TGAI	10, 11
Tier II						
Mutagenicity Testing (*In vivo* cytogenetics)						
870.5385 870.5895	*In vivo* Mammalian Cytogenetics	CR	CR	TGAI	TGAI	13
Developmental Toxicity						
870.3700	Prenatal developmental	CR	CR	TGAI	TGAI	9
Special Tests						
880.3550	Immunotoxicity	CR	CR	TGAI	TGAI	12, 13
Applicator/User Exposure						
875.1100	Dermal outdoor exposure	CR	CR	TGAI	TGAI	15
875.1200	Dermal indoor exposure	CR	CR	TGAI	TGAI	15
875.1300	Inhalation outdoor exposure	CR	CR	TGAI	TGAI	15
875.1400	Inhalation indoor exposure	CR	CR	TGAI	TGAI	15
875.1500	Biological monitoring	CR	CR	TGAI	TGAI	15
Tier III						
Chronic Testing/Special Testing						
880.3800	Immune response	CR	CR	TGAI	TGAI	14
870.3800	Reproduction and fertility effects	CR	CR	TGAI	TGAI	16
870.4100	Chronic oral - rodent and nonrodent	CR	CR	TGAI	TGAI	17
870.4200	Carcinogenicity - two species - rat and mouse preferred	CR	CR	TGAI	TGAI	18
870.5380	Mammalian spermatogonial chromosome aberration test	CR	CR	TGAI	TGAI	19
Special Testing						
870.7200	Companion animal safety	CR	CR	NR	TGAI or EP	20

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides human health assessment as referenced in the last column of the table in paragraph (d) of this section.

1. Required unless the test material is a gas or highly volatile (vapor pressure $>10^{-4}$torr (mm/Hg)).

2. Required unless the test material is corrosive to skin or has pH <2 or >11.5.

3. Required when the pesticide, under conditions of use, would result in respirable material (e.g., gas, volatile substance or aerosol/particulate), unless it is a straight chain lepidopteran pheromone.

4. Required if repeated contact with human skin is likely to occur under conditions of use.

5. Hypersensitivity incidents must be reported as adverse effects data.

6. Required for non-food uses that are likely to result in repeated oral exposure to humans.

7. Required to support uses involving purposeful application to the human skin or which would result in comparable prolonged human exposure to the product (e.g., insect repellents) and if any of the following criteria are met:

i. Data from a 90–day oral study are not required.

ii. The active ingredient is known or expected to be metabolized differently by the dermal route of exposure than by the oral route and the metabolite is of toxicological concern.

iii. The use pattern is such that the dermal route would be the primary route of exposure.

8. Required if there is a likelihood of significant levels of repeated inhalation exposure to the pesticide as a gas, vapor, or aerosol.

9. Required if the use of the product under widespread and commonly recognized practice may reasonably be expected to result in significant exposure to female humans (e.g., occupational exposure or repeated application of insect repellents directly to the skin). Tier II data is required on a different test species from Tier I data when

developmental effects are observed in the first study and information on species-to-species extrapolation is needed.

10. Required to support nonfood uses if either:

i. The use is likely to result in significant human exposure; or

ii. The active ingredient (or its metabolites) is structurally related to a known mutagen or belongs to any chemical class of compounds containing a known mutagen. Additional mutagenicity tests that may have been performed plus a complete reference list must also be submitted. Subsequent testing may be required based on the available evidence.

11. Choice of assay using either:

i. Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression or detection;

ii. Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgprt) gene locus, accompanied by an appropriate *in vitro* test for clastogenicity; or

iii. CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xprt) gene locus.

12. Required if there are effects on hematology, clinical chemistry, lymphoid organ weights, and histopathology are observed in the 90–day studies.

13. The micronucleus rodent bone marrow assay is preferred; however, rodent bone marrow assays using metaphase analysis (aberrations) are acceptable.

14. Required if adverse effects are observed in the Tier II immunotoxicity study. The protocol for evaluating adverse effects to the immune response should be developed after evaluating the effects noted in the immunotoxicity study.

15. These data are required when the data used for the human health assessment indicates that the biochemical may pose a potential hazard to the applicator/user.

16. Required if there is evidence of:

i. Endocrinological effects from the subchronic toxicity studies.

ii. Developmental effects in the prenatal developmental toxicity study(s), or

iii. Genotoxicity to mammals based on results from the mutagenicity tests.

The use of a combined study that utilizes the two-generation reproduction study in rodents (guideline 870.3800) as a basic protocol for the addition of other endpoints or functional assessments in the immature animal is encouraged.

17. Required if the potential for adverse chronic effects is indicated based on any of the following:

i. The subchronic effect level established in the following Tier I studies: 90–day oral toxicity study, 90–day dermal toxicity study, or 90–day inhalation toxicity study.

ii. The pesticide use pattern (e.g., rate, frequency, and site of application).

iii. The frequency and level of repeated human exposure that is expected.

18. Required if the product meets either of the following criteria:

i. The active ingredient (or any of its metabolites, degradation products, or impurities) produce(s) in Tier I subchronic studies a morphologic effect (e.g., hyperplasia or metaplasia) in any organ that potentially could lead to neoplastic change.

ii. Adverse cellular effects suggesting carcinogenic potential are observed in Tier II immunotoxicity and Tier III immune response study or in Tier II mammalian mutagenicity assays.

In addition, a 90–day range finding study in both rats and mice is required to determine the dose levels if carcinogenicity studies are required. If the mouse carcinogenicity study is not required, the 90–day mouse subchronic study is likewise not required.

19. Required if results from lower tiered mutation or reproductive studies indicate there is potential for chromosomal aberration to occur.

20. May be required if the product's use will result in exposure to domestic animals through, but not limited to, direct application or consumption of treated feed.

§ 158.2060 Biochemical pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms and fate data requirements for a particular biochemical pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section. In general, for all outdoor end-use products including turf, the following studies are required: one avian acute oral, one avian dietary, one acute freshwater fish, one acute freshwater invertebrate study, plant toxicity testing, and a honeybee acute contact study.

(2) The data in this section are not required for arthropod pheromones when applied at up to a maximum use rate of 150 grams active ingredient/acre/year except when the product is expected to be available to avian species (i.e., granular formulation).

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood/nonfeed crop. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and nonfood use. The remaining terrestrial uses include: forestry and residential outdoor use. Data are also required for the general use patterns of aquatic food and nonfood crop use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for biochemical pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
Tier I								
Avian Testing								
850.2100	Avian acute oral toxicity	R	R	CR	R	CR	TGAI, EP	1, 2, 3, 4

TABLE—BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/ Feed/ Nonfood	Food/ Nonfood	Food/ Nonfood		Food/ Nonfood		
850.2200	Avian dietary toxicity	R	R	CR	R	CR	TGAI, EP	1, 2, 3, 4
Aquatic Organism Testing								
850.1075	Fish acute toxicity, freshwater	R	R	CR	R	CR	TGAI, EP	2, 3, 4, 5
850.1010	Aquatic invertebrate acute toxicity, freshwater	R	R	CR	R	CR	TGAI, EP	2, 3, 5
Nontarget Plant Testing								
850.4100	Terrestrial Plant Toxicity, Seedling emergence	R	R	NR	R	NR	TGAI, EP	5
850.4150	Terrestrial Plant Toxicity, Vegetative vigor	R	R	NR	R	NR	TGAI, EP	5
Insect Testing								
880.4350	Nontarget Insect Testing	R	R	R	R	NR	TGAI	14
Tier II								
Environmental Fate Testing								
163-1 (835.1230)	Sediment and soil adsorption/ desorption for parent and degradates	CR	CR	CR	CR	NR	TGAI	6
163-1 (835.1240)	Soil column leaching	CR	CR	CR	CR	NR	TGAI	6
163-2 (835.1410)	Laboratory volatilization from soil	CR	NR	CR	CR	NR	TEP	7
161-1 (835.2120)	Hydrolysis	CR	CR	CR	CR	NR	TGAI	6
161-1 (835.4100)	Aerobic soil metabolism	CR	NR	CR	CR	NR	TGAI	6
161-2 (835.2240)	Photodegradation in water	CR	CR	CR	CR	NR	TGAI	6
161-3 (835.2410)	Photodegradation on soil	CR	NR	CR	CR	NR	TGAI	6
162-2 (835.4200)	Anaerobic soil metabolism	CR	NR	NR	NR	NR	TGAI	6
162-4 (835.4300)	Aerobic aquatic metabolism	CR	CR	CR	CR	NR	TGAI	6
162-3 (835.4400)	Anaerobic aquatic metabolism	CR	CR	NR	NR	NR	TGAI	6
880.4425	Dispenser - water leaching	CR	NR	CR	CR	NR	EP	8
Nontarget Plant								
850.4225	Seedling emergence	R	R	NR	R	NR	TGAI	9
850.4250	Vegetative vigor	R	R	NR	R	NR	TGAI	9
Tier III								
Aquatic Fauna Chronic, Life Cycle, and Field Studies								
850.1300 850.1400 850.1500	Freshwater fish/invertebrate testing	CR	CR	NR	CR	NR	TGAI	10

TABLE—BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/ Feed/ Nonfood	Food/ Nonfood	Food/ Nonfood		Food/ Nonfood		
850.1025 850.1035 850.1045 850.1055 850.1350 850.1400 850.1500	Marine/Estuarine fish/invertebrate animal testing	CR	CR	NR	CR	NR	TGAI	10
850.1950	Aquatic field fish/invertebrate testing	CR	CR	NR	CR	NR	EP	10
Terrestrial Wildlife								
850.2300	Avian Reproduction	CR	CR	NR	CR	NR	TGAI	11
850.2400	Wild mammal acute toxicity	CR	CR	NR	CR	NR	TGAI	11
850.2500	Terrestrial field testing	CR	CR	NR	CR	NR	EP	11
Beneficial Insects								
850.3040	Field testing for Pollinators	CR	CR	NR	CR	NR	TEP	12
Nontarget Plants								
850.4225 850.4250 850.4300 850.4450	Nontarget plant	CR	CR	NR	CR	NR	TGAI	13

(e) *Test notes*. The following test notes are applicable to the data requirements for biochemical pesticides nontarget organisms and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Required for the EP when any end-use formulation may contain other ingredients that may be toxic to nontarget organisms or to support arthropod pheromones that would be available to avian wildlife, (e.g., a granular product).

2. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, physical/chemical properties, production volume, and other pertinent factors.

3. Not required for any use groups if the pesticide is highly volatile (estimated volatility >5 X 10^{-5}atm m^3/mol).

4. Preferred test species are Upland game, waterfowl, or passerine for avian acute oral toxicity studies; Upland game and waterfowl for avian dietary studies; and coldwater fish species for acute freshwater fish studies.

5. Required for the EP when the end-use formulation may contain other ingredients that may be toxic to nontarget organisms.

6. Required on a case-by-case basis when results from Tier I studies indicate adverse effects.

7. Required when results of any one or more of the nontarget organism studies in Tier I indicate potential adverse effects on nontarget organisms and the pesticide is to be applied on land. In view of methdological difficulties with the study of photodegradation in air, prior consultation with the Agency regarding the protocol is recommended before the test is performed.

8. Required when results of any one or more of the nontarget organism studies in Tier I indicate potential adverse effects on nontarget organisms and the pesticide is to be applied in a passive dispenser.

9. Required to support registration of known phytotoxicants, i.e. herbicides, desiccants, defoliants, and plant growth regulators.

10. Required if environmental fate characteristics indicate that the estimated environmental concentration of the pesticide in the aquatic environment is >0.01 of any EC_{50} or LC_{50} determined in the aquatic nontarget organism testing.

11. Required if either of the following criteria are met:

i. Environmental fate characteristics indicate that the estimated concentration of the pesticide in the terrestrial environment is > 0.20 the avian dietary LC_{50} or equal to > 0.20 the avian oral single dose LD_{50} (converted to ppm).

ii. The pesticide or any of its metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in the avian or mammalian feed.

12. Required when results of Tier I nontarget organism studies indicate potential adverse effects on nontarget insects and results of Tier II tests indicate exposure of nontarget insects. Additional insect species may have to be tested if necessary to address issues raised by use patterns and potential exposure of important nontarget insect species, (e.g., threatened or endangered species).

13. Required if the product is expected to be transported from the site of application by air, soil, or water. The extent of movement would be determined by the results of the Tier II environmental fate studies.

14. Required depending on pesticide mode of action, method and timing of application, and results of any available efficacy data. Typically the honeybee acute toxicity guideline (guideline 850.3020) satisfies this requirement, however, additional nontarget insect species may have to be tested if necessary to address issues raised by use patterns and potential exposure of important nontarget insect species, (e.g., endangered species.)

§ 158.2070 Biochemical pesticides product performance data requirements.

Product performance data must be developed for all biochemical

pesticides. However, the Agency typically does not require applicants to submit such efficacy data unless the pesticide product bears a claim to control public health pests, such as pest microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

§ 158.2080 Experimental use permit data requirements—biochemical pesticides.

(a) Sections 158.2081 through 158.2084 describe the experimental use permit (EUP) data requirements for biochemical pesticides. Variations in the test conditions are identified within the test notes. Definitions that apply to all biochemical data requirements can be found in § 158.2000.

(b) For general information on the data requirement tables, see § 158.2010(b)-(f).

§ 158.2081 Experimental use permit biochemical pesticides product chemistry data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the product chemistry data requirements for a particular biochemical pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of the section.

(2) Depending on the results of the required product chemistry studies, appropriate use restrictions, labeling requirements, or special packaging requirements may be imposed.

(b) *Use patterns.* Product chemistry data are required for all pesticide products and are not use specific.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit biochemical pesticides product chemistry. The test notes are shown in paragraph (e) of this section .

TABLE—EUP BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Identity and Composition					
880.1100	Product identity and composition	R	TGAI, MP	TGAI, EP	1, 2
880.1200	Description of starting materials, production and formulation process	R	TGAI, MP	TGAI, EP	2, 3
880.1400	Discussion of formation of impurities	R	TGAI and MP	TGAI and EP	4
Analysis and Certified Limits					
830.1700	Preliminary analysis	CR	TGAI and MP	TGAI and EP	5, 8
830.1750	Certified limits	R	MP	EP	6
830.1800	Enforcement analytical method	R	MP	EP	7
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	8
830.6303	Physical state	R	TGAI and MP	TGAI and EP	8
830.6304	Odor	R	TGAI	TGAI	8
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	8, 17
830.6315	Flammability	CR	MP	EP	9
830.6317	Storage stability	R	MP	EP	--
830.6319	Miscibility	CR	MP	EP	10
830.6320	Corrosion characteristics	R	MP	EP	--

TABLE—EUP BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
830.7000	pH	CR	TGAI and MP	TGAI and EP	8, 11
830.7050	UV/Visible light absorption	R	TGAI	TGAI	--
830.7100	Viscosity	CR	MP	EP	12
830.7200	Melting point/melting range	CR	TGAI	TGAI	8, 13
830.7220	Boiling point/boiling range	CR	TGAI	TGAI	8, 14
830.7300	Density/relative density/bulk density	R	TGAI and MP	TGAI and EP	8, 18
830.7520	Particle size, fiber length, and diameter distribution	CR	TGAI	TGAI	8, 15
830.7550 830.7560 830.7570	Partition coefficient (n-Octanol /Water)	CR	TGAI	TGAI	16
830.7840	Water solubility	R	TGAI	TGAI	8
830.7950	Vapor pressure	R	TGAI	TGAI	8, 19

(e) *Test notes*. The following test notes are applicable to the data requirements for experimental use permit biochemical pesticides product chemistry and are referenced in the last column of the table in paragraph (d) of this section.

1. Data must be provided in accordance with § 158.320.
2. If the MP and EP are produced by an integrated formulation system (non-registered source), these data are also required on TGAI.
3. Data must be provided in accordance with § 158.325, § 158.330, and § 158.335.
4. Data must be provided in accordance with § 158.340.
5. Data must be provided in accordance with § 158.345. Also, required to support the registration of each manufacturing-use product (including registered TGAIs) and end-use products produced by an integrated formulation system. Data on other end-use products would be required on a case-by-case basis. For pesticides in the production stage, a preliminary product analytical method and data would suffice to support an experimental use permit.
6. Data must be provided in accordance with § 158.350.
7. Data must be provided in accordance with § 158.355.
8. If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI. EP testing may also be appropriate.
9. Required if the product contains combustible liquids.
10. Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.
11. Required if the test substance is soluble or dispersible in water.
12. Required if the product is a liquid.
13. Required when the technical chemical is a solid at room temperature.
14. Required when the technical chemical is a liquid at room temperature.
15. Required for water insoluble test substances (>10^{-6}g/l) and fibrous test substances with diameter ≥0.1 μm.
16. Required for organic chemicals unless they dissociate in water or are partially or completely soluble in water.
17. Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.
18. True density or specific density are required for all test substances. Data on bulk density is required for MPs or EPs that are solid at room temperature.
19. Not required for salts.

§ 158.2082 Experimental use permit biochemical pesticides residue data requirements table.

(a) *General*. Sections 158.100 through 158.130 describe how to use this table to determine the biochemical pesticides residue data requirements for a particular pesticide product and the substance that needs to be tested. These data requirements apply to all biochemical pesticides, i.e. naturally occurring insect repellents and attractants, semiochemicals (e.g., insect pheromones), natural and plant growth regulators. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns*. (1) Data are required or conditionally required for all pesticides used in or on food and for residential outdoor uses where food crops are grown. Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use. Data are also conditionally required for aquatic nonfood use if there is direct application to water that could subsequently result in exposure to food.

(2) Data are conditionally required for nonfood uses if pesticide residues may occur in food or feed as a result of the use. Data requirements for these nonfood uses would be determined on a case-by-case basis. For example, most products used in or near kitchens require residue data for risk assessment purposes even though tolerances may not be necessary in all cases.

(c) *Key*. R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing end-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates,and impurities of toxicological concern. All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Data table*. The following table shows the data requirements for biochemical pesticides residue. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES RESIDUE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns				Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse Food	Indoor Food		
		Food/Feed	Food				
Supporting Information							
860.1100	Chemical identity	CR	CR	CR	CR	TGAI	1, 2, 4
860.1200	Directions for use	CR	CR	CR	CR	--	1, 3, 4
Nature of Residue							
860.1300	Nature of the residue in plants	CR	CR	CR	CR	TGAI	1, 4, 5, 6
860.1300	Nature of the residue in livestock	CR	CR	CR	CR	TGAI or plant metabolite	1, 7, 8, 9, 13
Magnitude of the Residue							
860.1400	Potable water	NR	CR	NR	NR	TGAI	1, 11
860.1400	Fish	NR	CR	NR	NR	TGAI	1, 12
860.1400	Irrigated crops	NR	CR	NR	NR	TGAI	1, 13
860.1460	Food handling	NR	NR	NR	CR	TGAI	1, 14
860.1480	Meat/milk/poultry/eggs	CR	CR	CR	CR	TGAI or plant metabolites	1, 7, 8, 9
860.1500	Crop field trials	CR	CR	CR	CR	TEP	1, 3, 4
860.1520	Processed food/feed	CR	CR	CR	CR	TEP	1, 15
860.1540	Anticipated residues	CR	CR	CR	CR	Residue of concern	1, 9, 16
860.1550	Proposed tolerances	CR	CR	CR	CR	--	1, 17
860.1560	Reasonable grounds in support of the petition	CR	CR	CR	CR	--	1, 9
860.1650	Submittal of analytical reference standards	CR	CR	CR	CR	TGAI and residue of concern	9, 18

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides product chemistry and are referenced referenced in the last column of the table contained in paragraph (d) of this section.

1. Residue chemistry data requirements apply to biochemical pesticide products when Tier II or Tier III toxicology data are required, as specified for biochemical agents in the biochemical human health assessment data requirements, §158.2050.

2. The same chemical identity data are required for biochemical product chemistry data requirements,§158.2030 with an emphasis on impurities.

3. Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

4. Required for residential outdoor uses on food crops if the corresponding agricultural use is not approved or the residential use is expected to produce higher residues based on the label directions.

5. Required unless it is an arthropod pheromone applied at a rate less than or equal to 150 grams active ingredient per acre.

6. Required for indoor uses where the pesticide is applied directly to food, in order to determine metabolites and/or degradates. Not required when only indirect contact with food would occur (e.g., crack and crevice treatments).

7. Required when a pesticide is to be applied directly to livestock, to livestock premises, to livestock drinking water, or to crops used for livestock feed. If results from the plant metabolism study show differing metabolites in plants form those found in animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be required.

8. Livestock feeding studies are required whenever a pesticide residue is present in livestock feed or when direct application to livestock uses occurs.

9. Required if indoor use could result in pesticide residues in or on food or feed.

10. Data are required to determine whether FDA/USDA multiresidue methodology would detect and identify the pesticides and any metabolites.

11. Data are required whenever a pesticide may be applied directly to water, unless it can be demonstrated that the treated water would not be available for human or livestock consumption.

12. Data on fish are required for all pesticides applied directly to water inhabited, or which will be inhabited, by fish that may be caught or harvested for human consumption.

13. Data are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

14. Data are required whenever a pesticide may be used in food/feed handling establishments.

15. Data on the nature and level of residue in processed food/feed are required when detectible residues could potentially concentrate on processing thus requiring the

establishment of a separate tolerance higher than that of the raw agricultural commodity.

16 Anticipated residue data are required when the assumption of tolerance level residues would result in predicted exposure at an unsafe level of exposure. Data, using single serving samples of a raw agricultural commodity, on the level or residue in food as consumed would be used to obtain a more precise estimate of potential dietary exposure. These data may also include washing, cooking, processing or degradation studies as well as market basket surveys for a more precise residue determination.

17. The proposed tolerance must reflect the maximum residue likely to occur in crops, in meat, milk, poultry, or eggs.

18. Required when a residue analytical method is required.

§ 158.2083 Experimental use permit biochemical pesticides human health assessment data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the human health assessment data requirements for a particular biochemical pesticide product.

(2) The data in this section are not required for straight chain lepidopteran pheromones when applied up to a maximum use rate of 150 grams active ingredient/acre/year.

(b) *Use patterns.* (1) Food use patterns, in general, include products classified under the following general uses: terrestrial food crop use; terrestrial feed crop use; aquatic food crop use; greenhouse food crop use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use; aquatic nonfood residential use; aquatic nonfood outdoor use; aquatic nonfood industrial use; greenhouse nonfood crop use; forestry use; residential outdoor use; residential indoor use; indoor food use; indoor nonfood use; indoor medical use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit biochemical pesticides human health assessment. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES HUMAN HEALTH ASSESSMENT DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes
		Food	Nonfood	MP	EP	
Tier I						
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	TGAI and MP	TGAI and EP	1
870.1200	Acute dermal toxicity	R	R	TGAI and MP	TGAI and EP	1, 2
870.1300	Acute inhalation toxicity - rat	R	R	TGAI and MP	TGAI and EP	3
870.2400	Primary eye irritation - rabbit	R	R	TGAI and MP	TGAI and EP	2
870.2500	Primary dermal irritation	R	R	TGAI and MP	TGAI and EP	1, 2
none	Hypersensitivity incidents	R	R	All	All	4
Subchronic Testing						
870.3100	90-day oral (one species)	R	NR	TGAI	TGAI	--
Developmental Toxicity						
870.3700	Prenatal developmental - rat preferably	R	CR	TGAI	TGAI	5
Mutagenicity Testing						
870.5100	Bacterial reverse mutation test	R	CR	TGAI	TGAI	6
870.5300	*In vivo* mammalian cell assay	R	CR	TGAI	TGAI	6, 7
Tier II						
Developmental Toxicity						
870.3700	Prenatal developmental	CR	CR	TGAI	TGAI	5

(e) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit biochemical pesticides human health assessment as referenced in the last column of the table in paragraph (d) of this section.

1. Required unless the test material is a gas or highly volatile (vapor pressure > 10^{-4}torr (mm/Hg)).

2. Required unless the test material is corrosive to skin or has pH <2 or >11.5.

3. Required when the pesticide, under conditions of use, would result in respirable material (e.g., gas, volatile substance or aerosol/particulate), unless it is a straight chain lepidopteran pheromone.

4. Hypersensitivity incidents must be reported as adverse effects data.

5. Required if the use of the product under widespread and commonly recognized practice may reasonably be expected to result in significant exposure to female humans (e.g., occupational exposure or repeated application of insect repellents directly to the skin). Tier II data is required on a different test species from Tier I data when developmental effects are observed in the first study and information on species-to-species extrapolation is needed.

6. Required to support nonfood uses if either:

i. The use is likely to result in significant human exposure; or

ii. The active ingredient (or its metabolites) is structurally related to a known mutagen or belongs to any chemical class of compounds containing a known mutagen.

Additional mutagenicity tests that may have been performed plus a complete reference list must also be submitted. Subsequent testing may be required based on the available evidence.

7. Choice of assay using either:

i. Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression or detection;

ii. Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgprt) gene locus, accompanied by an appropriate *in vivo* test for clastogenicity; or

iii. CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xprt) gene locus.

§ 158.2084 Experimental use permit biochemical pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms and fate data requirements for a particular biochemical pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section. In general, for all outdoor end-use products including turf, the following studies are required: one avian acute oral, one avian dietary, one acute freshwater fish, and one acute freshwater invertebrate study.

(2) The data in this section are not required for arthropod pheromones when applied at up to a maximum use rate of 150 grams active ingredient/acre/year except when the product is expected to be available to avian species (i.e., granular formulation).

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood/nonfeed crop. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and nonfood use. The remaining terrestrial uses include forestry and residential outdoor use. Data are also required for the general use patterns of aquatic food and nonfood crop use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit biochemical pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
Tier I								
Avian Testing								
850.2100	Avian acute oral toxicity	R	R	NR	R	NR	TGAI, EP	1, 2, 3
850.2200	Avian dietary toxicity	R	R	NR	R	NR	TGAI, EP	1, 2, 3
Aquatic Organism Testing								
850.1075	Fish acute toxicity, freshwater	R	R	NR	R	NR	TGAI, EP	2, 3, 4
850.1010	Aquatic invertebrate acute toxicity, freshwater	R	R	NR	R	NR	TGAI, EP	2, 4

(e) *Test notes*. The following test notes are applicable to the data requirements for experimental use permit biochemical pesticides nontarget organisms and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Required for the EP when any end-use formulation may contain other ingredients that may be toxic to nontarget organisms or to support arthropod pheromones that would be available to avian wildlife, (e.g., a granular product).

2. Not required for any use groups if the pesticide is highly volatile (estimated volatility >5 X 10^{-5}atm m^3/mol).

3. Preferred test species are: upland game, waterfowl, or passerine for avian acute oral toxicity studies; upland game or waterfowl for avian dietary studies; and coldwater fish for acute freshwater fish studies.

4. Required for the EP when the end-use formulation may contain other ingredients that may be toxic to nontarget organisms.

Subpart V—Microbial Pesticides

§ 158.2100 Microbial pesticides definition and applicability.

(a) This subpart applies to all living or dead microbial pesticides as described in paragraphs (b) and (c) of this section.

(b) *Definition*. *Microbial pesticide* is a microbial agent intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, that:

(1) Is a eucaryotic microorganism including, but not limited to, protozoa, algae, and fungi;

(2) Is a procaryotic microorganism, including, but not limited to, Eubacteria and Archaebacteria; or

(3) Is a parasitically replicating microscopic element, including, but not limited to, viruses.

(c) *Applicability*. (1) This part applies to microbial pesticides as specified in paragraphs (c)(2), (3) and (4) of this section.

(2) Each new isolate of a microbial pesticide is treated as a new strain and must be registered independently of any similar registered microbial pesticide strain and supported by data required in this subpart.

(3) Genetically modified microbial pesticides may be subject to additional data or information requirements on a case-by-case basis depending on the particular microbial agent and/or its parental strains, the proposed pesticide use pattern, and the manner and extent to which the organism has been genetically modified.

(4) Pest control organisms such as insect predators, nematodes, and macroscopic parasites are exempt from the requirements of FIFRA as authorized by section 25(b) of FIFRA and specified in § 152.20 (a) of this chapter.

§ 158.2110 Microbial pesticides data requirements.

(a) For all microbial pesticides. (1) The following § 158.2120 through § 158.2150 identify the data requirements that are required to support registration of microbial pesticides. The variations in the test conditions are identified within the test notes.

(2) Each data table includes ''use patterns'' under which the individual data are required, with variations including all use patterns, food and nonfood uses for terrestrial and aquatic applications, greenhouse, indoor, forestry, and residential outdoor applications under certain circumstances.

(3) The categories for each data requirement are ''R,'' which stands for required, and ''CR'' which stands for conditionally required. If a bracket appears around the ''R'' or ''CR,'' the data are required for both the registration and experimental use permit requests. Generally, ''R'' indicates that the data are more likely required than for those data requirements with ''CR.'' However, in each case, the regulatory text preceding the data table and the test notes following the data table must be used to determine whether the data requirement must be satisfied.

(4) Each table identifies the test substance that is required to be tested to satisfy the data requirement. Test substances may include: technical grade active ingredient (TGAI), manufacturing-use product (MP), end-use product (EP), typical end-use product (TEP), residue of concern, and pure active ingredient (PAI) or all of the above (All). Commas between the test substances (i.e., TGAI, EP) indicate that data may be required on the TGAI or EP or both depending on the conditions set forth in the test note. Data requirements which list two test substances (i.e., TGAI and EP) indicate that both are required to be tested. Data requirements that list only MP as the test substance apply to products containing solely the technical grade of the active ingredient and manufacturing-use products to which other ingredients have been intentionally added. Data requirements listing the EP as the test substance apply to any EP with an ingredient in the end-use formulation other than the active ingredient that is expected to enhance the toxicity of the product.

(b) Additional data requirements for genetically modified microbial pesticides. Additional requirements for genetically modified microbial pesticides may include but are not limited to: genetic engineering techniques used; the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene); information on the control region of the gene in question; a description of the ''new'' traits or characteristics that are intended to be expressed; tests to evaluate genetic stability and exchange; and selected Tier II environmental expression and toxicology tests.

§ 158.2120 Microbial pesticides product analysis data requirements table.

(a) *General*. Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test are identified in paragraph (d) of this section, and the test notes appear in paragraph (e) of this section.

(b) *Key*. R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(c) *Table*. The following table shows the data requirements for microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE—MICROBIAL PESTICIDES PRODUCT ANALYSIS DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product Identity	R	MP	EP	--
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	--
	Deposition of a sample in a nationally recognized culture collection	R	TGAI	TGAI	--
885.1300	Discussion of formation of unintentional ingredients	R	TGAI and MP	TGAI and EP	--
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	1
885.1500	Certification of limits	R	MP	EP	--
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	--
830.6303	Physical state	R	TGAI	TGAI	--
830.6304	Odor	R	TGAI	TGAI	--
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	--
830.6317	Storage stability	R	TGAI and MP	TGAI and EP	--
830.6319	Miscibility	R	MP	EP	2
830.6320	Corrosion Characteristics	R	MP	EP	3
830.7000	pH	R	TGAI	TGAI	--
830.7100	Viscosity	R	MP	EP	4
830.7300	Density/relative density/bulk density (specific gravity)	R	TGAI	TGAI	--

(d) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides product analysis as referenced in the last column of the table contained in paragraph (c) of this section.

1. Required to support registration of each manufacturing-use product and end-use product. This analysis must be conducted at the point in the production process after which there would be no potential for microbial contamination or microbial regrowth. For full registration, generally an analysis of samples is a compilation of batches, over a period of time, depending on the frequency of manufacturing.

2. Only required for emulsifiable liquid forms of microbial pesticides.

3. Required when microbial pesticides are packaged in metal, plastic, or paper containers.

4. Only required for liquid forms of microbial pesticides.

§ 158.2130 Microbial pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the residue chemistry data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test appear in paragraph (d) of this section, and the procedures appear in paragraph (e) of this section.

(b) *Key.* R=required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for microbial pesticides residue. The test notes are shown in paragraph (d) of this section.

TABLE—MICROBIAL PESTICIDES RESIDUE DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance Data to Support MP or EP	Test Notes
885.2100	Chemical Identity	CR	EP	1
885.2200	Nature of the Residue in plants	CR	EP	1
885.2250	Nature of the Residue in animals	CR	EP	1
885.2300	Analytical methods - plants	CR	TGAI	1
885.2350	Analytical methods - animals	CR	TGAI	1
885.2400	Storage Stability	CR	EP	1
885.2500	Magnitude of residue in plants	CR	EP	1
885.2550	Magnitude of residues in meat, milk, poultry, eggs	CR	EP	1
885.2600	Magnitude of residues in potable water, fish, and irrigated crops	CR	EP	1

(d) *Test notes*. The following test note is applicable to the data requirements for microbial pesticides residue as referenced in the last column of the table contained in paragraph (c) of this section.

1. Required when the results of testing:

i. Indicate the potential to cause adverse human health effects or the product characterization indicates the microbial pesticide has a significant potential to produce a mammalian toxin; and

ii. The use pattern is such that residues may be present in or on food or feed crops.

§ 158.2140 Microbial pesticides toxicology data requirements table.

(a) *General*. Sections 158.100 through 158.130 describe how to use this table to determine the toxicology data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (d) of this section.

(b) *Key*. R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table*. The following table shows the data requirements for microbial pesticides toxicology. The test notes are shown in paragraph (d) of this section.

TABLE—MICROBIAL PESTICIDES TOXICOLOGY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance	Test Notes
Tier I				
885.3050	Acute oral toxicity/pathogenicity	R	TGAI	1
885.3150	Acute pulmonary toxicity/pathogenicity	R	TGAI	--
885.3200	Acute injection toxicity/pathogenicity/(intravenous) Acute injectiont toxicity/pathogenicity/(intraperitoneal)	R	TGAI	2
885.3400	Hypersensitivity incidents	R	All	3
885.3500	Cell culture	R	TGAI	4
870.1100	Acute oral toxicity	R	MP , EP	1, 5
870.1200	Acute dermal toxicity	R	MP , EP	5
870.1300	Acute inhalation toxicity	R	MP , EP	5, 6
870.2400	Acute eye irritation	R	MP , EP	5
870.2500	Primary dermal irritation	R	MP , EP	5
Tier II				
885.3550	Acute toxicology	CR	TGAI	7
885.3600	Subchronic toxicity/pathogenicity	CR	TGAI	8

TABLE—MICROBIAL PESTICIDES TOXICOLOGY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance	Test Notes
Tier III				
885.3650	Reproductive fertility effects	CR	TGAI	9, 13
870.4200	Carcinogenicity	CR	TGAI	10, 13
870.7800	Immunotoxicity	CR	TGAI	11, 13
885.3000	Infectivity/pathogenicity analysis	CR	TGAI	12, 13

(d) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides toxicology as referenced in the last column of the table contained in paragraph (c) of this section:

1. The acute oral toxicity/pathogenicity study is required to support the TGAI. However, it can be combined with the unit dose portion of the acute oral toxicity study, with an EP or MP test material to fulfill the requirement for the TGAI and the MP or EP in a single study, if the new protocol is designed to address the endpoints of concern.

2. Data not required for products whose active ingredient is a virus. For test materials whose size or consistency may prevent use of an intravenous injection, the intraperitoneal injection procedure may be employed.

3. Hypersensitivity incidents, including immediate type and delayed-type reactions of humans or domestic animals, occur during the testing or production of the TGAI, MP, or EP, or are otherwise known to the applicant must be reported if they occur.

4. Data must be submitted only for products whose active ingredient is a virus.

5. The 870 series studies for the MP and EP are intended to provide data on the acute toxicity of the product. Waivers for any or all of these studies may be granted when the applicant can demonstrate that the combination of inert ingredients is not likely to pose any significant human health risks. Where appropriate, the limit dose approach to testing is recommended.

6. Required when the product consists of, or under conditions of use would result in, an inhalable material (e.g., gas, volatile substances, or aerosol particulate).

7. Data required when significant toxicity, in the absence of pathogenicity and significant infectivity, is observed in acute oral, injection, or pulmonary studies (Tier I). Route(s) of exposure correspond to route(s) where toxicity was observed in Tier I studies. The toxic component of the TGAI is to be tested.

8. Data required when significant infectivity and/or unusual persistence is observed in the absence of pathogenicity or toxicity in Tier I studies. Routes of exposure (oral and/or pulmonary) correspond to routes in Tier I studies where adverse effects were noted. Data may also be required to evaluate adverse effects due to microbial contaminants or to toxic byproducts.

9. Data are required when one or more of the following criteria are met:

i. Significant infectivity of the microbial pest control agent (MPCA) was observed in test animals in the Tier II subchronic study and in which no significant signs of toxicity or pathogenicity were observed.

ii. The microbial pesticide is a virus which can persist or replicate in mammalian cell culture lines.

iii. The microbial pesticide is not amenable to thorough taxonomic classification, and is related to organisms known to be parasitic for mammalian cells.

iv. The microbial pesticide preparation is not well purified, and may contain contaminants which are parasitic for mammals.

10. Data may be required for products known to contain or suspected to contain carcinogenic viruses or for microbial components that are identified as having significant toxicity in Tier II testing.

11. Data may be required for products known to contain or suspected to contain viruses that can interact in an adverse manner with components of the mammalian immune system.

12. An analysis of human infectivity/pathogenicity potential using scientific literature, genomic analysis, and/or actual specific cell culture/animal data may be required for products known to contain or suspected of containing intracellular parasites of mammalian cells for products that exhibit pathogenic characteristics in Tier I and/or Tier II, for products which are closely related to known human pathogens based on the product analysis data, or for known human pathogens that have been ''disarmed'' or rendered non-pathogenic for humans.

13. Test standards may have to be modified depending on the characteristics of the microorganism. Requirements may vary for these studies depending on the active ingredient being tested. Consultation with the Agency is advised before performing these Tier III studies.

§ 158.2150 Microbial pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms data requirements for a particular microbial pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* Aquatic uses include: food and feed, nonfood uses (e.g., outdoor, residential, and industrial). Terrestrial uses include: Food, Feed, Non-Food, Forestry, Residential outdoor, greenhouse (food and food), Indoor (food and nonfood), and Industrial.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for microbial pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
		Food/ Feed	Nonfood	Food/ Feed/ Nonfood	Forestry	Residential Outdoor	Greenhouse Food/ Nonfood	Indoor Food/ Nonfood	Industrial		
Tier I											
885.4050	Avian oral toxicity	R	R	R	R	R	CR	CR	CR	TGAI	1, 2
885.4100	Avian inhalation toxicity/ pathogenicity	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	1, 2, 3
885.4150	Wild mammal toxicity/ pathogenicity	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	1, 4
885.4200	Freshwater fish toxicity/ pathogenicity	R	R	R	R	CR	CR	CR	CR	TGAI or TEP	1, 2, 5
885.4240	Freshwater invertebrate toxicity/ pathogenicity	R	R	R	R	CR	CR	CR	CR	TGAI or TEP	1, 2, 5
885.4280	Estuarine/Marine fish testing Estuarine and marine invertebrate testing	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	1, 6
885.4300	Nontarget plant testing	CR	CR	CR	R	CR	NR	CR	CR	TEP	1, 7
885.4340	Nontarget insect testing	R	R	R	R	R	CR	NR	CR	TGAI	1, 8
885.4380	Honey bee testing	R	R	R	R	R	CR	NR	CR	TGAI	1
Tier II											
885.5200	Terrestrial environmental expression tests	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	9
885.5300	Freshwater environmental expression tests	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	10
885.5400	Marine or estuarine environmental expression tests	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	11, 12
Tier III											
885.4600	Avian chronic pathogenicity and reproduction test	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	12, 13
885.4650	Aquatic invertebrate range testing	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	12, 14
885.4700	Fish life cycle studies	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	12, 14
885.4750	Aquatic ecosystem test	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	15
Tier IV											
850.2500 850.1950	Field testing for terrestrial wildlife and Field testing for aquatic organisms	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	11, 16
850.2500	Simulated or actual field tests (birds, mammals)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 17, 20

TABLE—MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
		Food/ Feed	Nonfood	Food/ Feed/ Nonfood	Forestry	Residential Outdoor	Greenhouse Food/ Nonfood	Indoor Food/ Nonfood	Industrial		
850.1950	Simulated or actual field test (aquatic organisms)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20
850.2500	Simulated or actual field tests (insect predators, parasites)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20
850.3040	Simulated or actual field tests (insect pollinators)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20
850.4300	Simulated or actual field tests (plants)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20

(e) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides nontarget organism and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors.

2. The preferred species for the avian oral study is either the upland game or waterfowl. The preferred species for the avian inhalation toxicity/pathogenicity study and the avian chronic toxicity/pathogenicity study is the upland game. There is also the option to test the passerine if there is a concern. The coldwater fish is preferred for freshwater fish testing. However, two species (coldwater and warmwater fish species are the preferred species) must be tested for uses involving direct freshwater exposure. Freshwater invertebrate testing is also required.

3. Data required when the nature of the microbial pesticide and/or its toxins indicates potential pathogenicity to birds.

4. Required on a case-by-case basis if results of tests required by § 158.2140 are inadequate or inappropriate for assessment of hazards to wild mammals.

5. Required when there will be significant exposure to aquatic organisms (fish and invertebrates).

6. Required if the product is intended for direct application into the estuarine or marine environment or expected to enter this environment in significant concentrations because of expected use or mobility pattern.

7. Required if the microbial pesticide is taxonomically related to a known plant pathogen.

8. Data are not required unless an active microbial ingredient controls the target insect pest by a mechanism of infectivity; i.e. may create an epizootic condition in nontarget insects.

9. Required if toxic or pathogenic effects are observed in one or more of the following tests for microbial pesticides:

i. Avian acute oral or avian inhalation studies.

ii. Wild mammal studies.

iii. Nontarget plant studies (terrestrial).

iv. Honey bee studies.

v. Nontarget insect studies.

10. Required when toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents:

i. Freshwater fish studies.

ii. Freshwater invertebrate studies.

iii. Nontarget plant studies (aquatic).

11. Required if product is applied on land or in fresh water or marine/estuarine environments and toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pesticides:

i. Estuarine and marine animal toxicity and pathogenicity.

ii. Plant studies - estuarine or marine species.

12. An appropriate dose-response toxicity test is required when toxic effects on nontarget terrestrial wildlife or aquatic organisms (including plants) are reported in one or more Tier I tests and results of Tier II tests indicate exposure of the microbial agent to the affected nontarget terrestrial wildlife or aquatic organisms. The protocols for these tests may have to be modified in accordance with results from the nontarget organism and environmental expression studies.

13. Required when one or more of the following are present:

i. Pathogenic effects are observed in Tier I avian studies.

ii. Tier II environmental expression testing indicate that long-term exposure of terrestrial animals is likely.

14. Required when product is intended for use in water or expected to be transported to water from the intended use site, and when pathogenicity or infectivity was observed in Tier I aquatic studies.

15. Required if, after an analysis of the microbial pesticide's ability to survive and multiply in the environment and what ecological habitat it would occupy, the intended use patterns, and the results of previous nontarget organisms and environmental expression tests, it is determined that use of the microbial agent may result in adverse effects on the nontarget organisms in aquatic environments. Testing is to determine if applications of the microbial pest control would be expected to disrupt the balance of populations in the target ecosystem.

16. Tier IV studies may be conducted as a condition of registration as post-registration monitoring if the potential for unreasonable adverse effects appears to be minimal during that period of use due to implementation of mitigation measures.

17. Required when both of the following conditions occur:

i. Pathogenic effects observed at actual or expected field residue exposure levels are reported in Tier III; and

ii. The Agency determines that quarantine methods would not prevent the microbial pesticide from contaminating areas adjacent to the test area.

18. Short term simulated or actual field studies are required when it is determined that the product is likely to cause adverse short-term or acute effects, based on consideration of available laboratory data, use patterns, and exposure rates.

19. Data from a long-term simulated field test (e.g., where reproduction and growth of confined populations are observed) and/or an actual field test (e.g., where reproduction and growth of natural populations are observed) are required if laboratory data indicate that adverse long-term, cumulative, or life-cycle effects may result from intended use.

20. Since test standards would be developed on a case-by-case basis, consultation with the Agency and development of a protocol is advised before performing these Tier IV studies.

§ 158.2160 Microbial pesticides product performance data requirements.

Product performance data must be developed for all microbial pesticides. However, the Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control public health pests, such as pest microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

§ 158.2170 Experimental use permit data requirements—microbial pesticides.

(a) For all microbial pesticides. (1) The following § 158.2171 through § 158.2174 identify the data requirements that are required to support experimental use permits for microbial pesticides. The variations in the test conditions are identified within the test notes.

(2) For general information on the data requirement tables, see § 158.2110(a)(2)-(4).

(b) Additional data requirements for genetically modified microbial pesticides. Additional requirements for genetically modified microbial pesticides may include but are not limited to: genetic engineering techniques used; the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene); information on the control region of the gene in question; a description of the ''new'' traits or characteristics that are intended to be expressed; tests to evaluate genetic stability and exchange; and selected Tier II environmental expression and toxicology tests.

§ 158.2171 Experimental use permit microbial pesticides product analysis data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test are identified in (d) of this section, and the test notes appear in paragraph (e) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for experimental use permit microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PRODUCT ANALYSIS DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product Identity	R	MP	EP	--
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	1, 2
885.1300	Deposition of a sample in a nationally recognized culture collection	R	TGAI	TGAI	--
	Discussion of formation of unintentional ingredients	R	TGAI and MP	TGAI and EP	2
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	2, 3
885.1500	Certification of limits	R	MP	EP	--
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	--
830.6303	Physical state	R	TGAI	TGAI	--
830.6304	Odor	R	TGAI	TGAI	--
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	--
830.6317	Storage stability	R	TGAI and MP	TGAI and EP	--
830.6319	Miscibility	R	MP	EP	4

TABLE—EUP MICROBIAL PRODUCT ANALYSIS DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
830.6320	Corrosion Characteristics	R	MP	EP	5
830.7000	pH	R	TGAI	TGAI	--
830.7100	Viscosity	R	MP	EP	6
830.7300	Density/relative density/bulk density (specific gravity)	R	TGAI	TGAI	--

(d) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit microbial pesticides product analysis as referenced in the last column of the table contained in paragraph (c) of this section.

1. If an experimental use permit is being sought, and if the pesticide is not already under full-scale production, a schematic diagram and/or description of the manufacturing process suffices.

2. If an experimental use permit is being sought, and if the product is not already under full-scale production, a discussion of unintentional ingredients is required to be submitted to the extent this information is available.

3. Required to support registration of each manufacturing-use product and end-use product. This analysis must be conducted at the point in the production process after which there would be no potential for microbial contamination or microbial regrowth. For pesticides in the production stage, a preliminary product analytical method and data would suffice to support an experimental use permit. For full registration, generally an analysis of samples is a compilation of batches, over a period of time, depending on the frequency of manufacturing.

4. Only required for emulsifiable liquid forms of microbial pesticides.

5. Required when microbial pesticides are packaged in metal, plastic, or paper containers.

6. Only required for liquid forms of microbial pesticides.

§ 158.2172 Experimental use permit microbial pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the residue chemistry data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test appear in (d) of this section, and the procedures appear in paragraph (e) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for experimental use permit microbial pesticides residue. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PESTICIDES RESIDUE DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance Data to Support MP or EP	Test Notes
885.2100	Chemical Identity	CR	EP	1
885.2200	Nature of the Residue in plants	CR	EP	1
885.2250	Nature of the Residue in animals	CR	EP	1
885.2300	Analytical methods - plants	CR	TGAI	1
885.2350	Analytical methods-animals	CR	TGAI	1
885.2400	Storage Stability	CR	EP	1
885.2500	Magnitude of residue in plants	CR	EP	1
885.2550	Magnitude of residues in meat, milk, poultry, eggs	CR	EP	1
885.2600	Magnitude of residues in potable water, fish, and irrigated crops	CR	EP	1

(d) *Test notes.* The following test note is applicable to the data requirements for experimental use permit microbial pesticides residue as referenced in the last column of the table contained in paragraph (c) of this section.

1. Required when the results of testing:

i. Indicate the potential to cause adverse human health effects or the product characterization indicates the microbial pesticide has a significant potential to produce a mammalian toxin; and

ii. The use pattern is such that residues may be present in or on food or feed crops.

§ 158.2173 Experimental use permit microbial pesticides toxicology data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the toxicology data requirements for a particular microbial pesticide product. Notes that apply to

an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (d) of this section.

(b) *Key*. R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table*. The following table shows the data requirements for microbial pesticide toxicology. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PESTICIDES TOXICOLOGY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance	Test Notes
885.3050	Acute oral toxicity/pathogenicity	R	TGAI	1
885.3150	Acute pulmonary toxicity/pathogenicity	R	TGAI	--
885.3200	Acute injection toxicity/pathogenicity/(intravenous) Acute injection toxicity/pathogenicity/(intraperitoneal)	R	TGAI	2
885.3400	Hypersensitivity incidents	R	All	3
885.3500	Cell culture	R	TGAI	4
870.1100	Acute oral toxicity	R	MP, EP	1, 5
870.1200	Acute dermal toxicity	R	MP, EP	5
870.1300	Acute inhalation toxicity	R	MP, EP	5, 6
870.2400	Acute eye irritation	R	MP, EP	5
870.2500	Primary dermal irritation	CR	MP, EP	5

(d) *Test notes*. The following test notes are applicable to the data requirements for experimental use permit microbial pesticides toxicology as referenced in the last column of the table contained in paragraph (c) of this section:

1. The acute oral toxicity/pathogenicity study is required to support the TGAI. However, it can be combined with the unit dose portion of the acute oral toxicity study, with an EP or MP test material to fulfill the requirement for the TGAI and the MP or EP in a single study, if the new protocol is designed to address the endpoints of concern.

2. Data not required for products whose active ingredient is a virus. For test materials whose size or consistency may prevent use of an intravenous injection, the intraperitoneal injection procedure may be employed.

3. Hypersensitivity incidents, including immediate type and delayed type reactions of humans or domestic animals occur during the testing or production of the TGAI, MP, or EP, or are otherwise known to the applicant must be reported if they occur.

4. Data must be submitted only for products whose active ingredient is a virus.

5. The 870 series studies for the MP and EP are intended to provide data on the acute toxicity of the product. Waivers for any or all of these studies may be granted when the applicant can demonstrate that the combination of inert ingredients is not likely to pose any significant human health risks. Where appropriate, the limit dose approach to testing is recommended.

6. Required when the product consists of, or under conditions of use that would result in an inhalable material (e.g., gas, volatile substances, or aerosol particulate).

§ 158.2174 Experimental use permit microbial pesticides nontarget organisms and environmental fate data requirements table.

(a) *General*. Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms data requirements for a particular microbial pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns*. Aquatic uses include: food and feed, nonfood uses (e.g., outdoor, residential, and industrial). Terrestrial uses include: Food, Feed, Non-Food, Forestry, Residential outdoor, greenhouse (food and food), Indoor (food and nonfood), and Industrial.

(c) *Key*. R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table*. The following table shows the data requirements for experimental use permit microbial pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—EUP MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
		Food/ Feed	Nonfood	Food/ Feed/ Nonfood	Forestry	Residential Outdoor	Greenhouse Food/ Nonfood	Indoor Food/ Nonfood	Industrial		
885.4050	Avian oral toxicity	NR	R	R	R	R	NR	NR	NR	TGAI	1, 2
885.4200	Freshwater fish toxicity/ pathogenicity	NR	R	R	R	NR	NR	NR	NR	TGAI	1, 2, 3
885.4240	Freshwater invertebrate toxicity/pathogenicity	NR	R	R	R	NR	NR	NR	NR	TGAI	1, 2, 3
885.4300	Nontarget plant testing	NR	NR	NR	R	NR	NR	NR	NR	TEP	1, 4
885.4340	Nontarget insect testing	R	R	R	R	NR	NR	NR	NR	TGAI	1, 5
885.4380	Honey bee testing	R	R	R	R	NR	NR	NR	NR	TGAI	1

(e) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides nontarget organism and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors. Tests to support EUP's are based on the application timing and acreage.

2. The preferred species for the avian oral study is either the upland game or waterfowl. The preferred species for the avian inhalation toxicity/pathogenicity study and the avian chronic toxicity/pathogenicity study is the upland game. There is also the option to test a passerine species if there is a concern. The coldwater fish is preferred for freshwater fish testing. However, two species (coldwater and warmwater fish are the preferred species) must be tested for uses involving direct freshwater exposure. Freshwater invertebrates are preferred for invertebrate testing.

3. Required when there will be significant exposure to aquatic organisms (fish and invertebrates).

4. Required if the microbial pesticide is taxonomically related to a known plant pathogen.

5. Data are not required unless an active microbial ingredient controls the target insect pest by a mechanism of infectivity; i.e. may create an epizootic condition in nontarget insects.

[FR Doc. E7–20828 Filed 10–25–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152, 156, 159, 160, 168 and 172

[EPA–HQ–OPP–2004–0387; FRL–8114–1]

Pesticide Data Requirements; Technical Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document makes technical changes and revises cross references in the Code of Federal Regulations (CFR) to reflect changes in pesticide data requirements being promulgated elsewhere in today's **Federal Register**. These technical changes are solely to conform other parts of the CFR to the new rules, and have no substantive impact on any requirements. This regulation is a technical amendment which requires no opportunity for comment or public participation.

DATES: This final rule is effective December 26, 2007.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2004–0387. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Public Docket, in Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Jean Frane, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5944; fax number: (703) 305–5884; e-mail address: *frane.jean@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me

You may be potentially affected by this action if you are a producer or registrant of a pesticide product. This action may also affect any person or company who might petition the Agency for new tolerances, hold a pesticide registration with existing tolerances, or any person or company

who is interested in obtaining or retaining a tolerance in the absence of a registration, that is, an import tolerance. Potentially affected entities may include, but are not limited to:

• Pesticide Producers (NAICS code 32532), e.g., pesticide manufacturers or formulators of pesticide products, importers or any person or company who seeks to register a pesticide or to obtain a tolerance for a pesticide.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) code has been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the persons listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

In the **Federal Register** of March 11, 2005 [70 FR 12276] and March 8, 2006 [71 FR 12072], EPA proposed to amend pesticide data requirements in 40 CFR part 158 for conventional pesticides and for biochemical and microbial pesticides, respectively. EPA is today issuing final rules for both proposals. In order to preserve existing data requirements for antimicrobial pesticides, that were contained in part 158, but not proposed for revision, EPA issued a final rule on October 24, 2007, transferring the bulk of current part 158 to new part 161. Together part 158 and part 161 contain the entirety of pesticide data requirements previously contained only in part 158.

This final rule makes certain technical changes and corrects cross-references elsewhere in pesticide regulations to conform to new parts 161 and 158. By issuing a separate technical changes rule, EPA intends that the promulgation of the substantive revisions for conventional, biochemical and microbial pesticide data requirements will be straightforward without confusing technical changes. The key changes are:

1. *Formulators' Exemption.* EPA has consolidated requirements and policies for the formulators' exemption into part 152. EPA has combined existing material from § 152.85 and § 158.50 in one location (§ 152.85) and made minor conforming changes to reflect the consolidation. The consolidation is discussed in detail in the final rule for conventional pesticides.

2. *Cross-reference changes.* Cross-references in parts 152, 156, 159, 160, 168 and 172 are being revised to reflect the new data requirements structure of part 158 and part 161. The majority of these changes reflect the addition of new part 161 for antimicrobial pesticides. Others are revised to reflect the new definition of biochemical or microbial pesticide.

III. Why are these Technical Revisions Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 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 final rule without providing notice and an opportunity for public comment. EPA has determined that it is unnecessary to make today's rule final without prior proposal and opportunity for comment, because EPA is simply making corrections to cross-references for accuracy. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

IV. Regulatory Assessment Requirements

This rule makes technical changes and cross-reference corrections in the EPA regulations governing pesticides. The amendments are administrative in nature and, for the most part, amend the CFR so that it is consistent with regulations concerning data requirements being promulgated elsewhere in this issue of the **Federal Register**. Other than making EPA regulations more accurate, these amendments are not expected to have any impact on regulated parties or the public.

Accordingly, these amendments are not subject to review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), as a significant regulatory action. Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This 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 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 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 (RFA) (5 U.S.C. 601 *et seq*).

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 rule is directed at pesticide manufacturers and others who seek to register, amend or maintain a registration or to establish, modify, or revoke pesticide tolerances or exemptions, not States. 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. Congressional Review Act

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 the 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 Part 152

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

List of Subjects in 40 CFR Part 156

Environmental protection, Labeling, Pesticides and pests, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 159

Environmental protection, Pesticides and pests, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 160

Environmental protection, Laboratories, Pesticides and pests, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 168

Environmental protection, Administrative practice and procedure, Advertising, Exports, Labeling, Pesticides and pests, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 172

Environmental protection, Intergovernmental relations, Labeling, Pesticides and pests, Reporting and recordkeeping requirements, Research.

Dated: October 11, 2007.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 152—[AMENDED]

■ 1. 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.

■ 2. Section 152.20 is amended by revising paragraph (a)(3) to read as follows:

§ 152.20 Exemptions for pesticides regulated by another Federal agency.

* * * * *

(a) * * *

(3) The following biological control agents are not exempt from FIFRA requirements:

(i) A eucaryotic microorganism including, but not limited to, protozoa, algae and fungi;

(ii) A procaryotic microorganism including, but not limited to, Eubacteria and Archaebacteria; or

(iii) A parasitically-replicating microscopic element, including, but not limited to, viruses.

* * * * *

■ 3. Section 152.43 is amended by revising paragraph (b)(4) to read as follows:

§ 152.43 Alternative formulations.

* * * * *

(b) * * *

(4) The analytical method required under § 158.355 of this chapter must be suitable for use on both the basic formulation and the alternate formulation.

* * * * *

■ 4. Amend § 152.50 in paragraph (f)(1) by revising the reference to ''FIFRA sec. 3(c)(1)(D)'' to read ''FIFRA sec. 3(c)(1)(F)'', and by revising paragraph (c) and paragraph (f)(2) to read as follows:

§ 152.50 Contents of application.

* * * * *

(c) *Summary of the application.* Each application must include a list of the data submitted with the application, together with a brief description of the results of the studies. The list of data submitted may be the same as the list required by § 158.32 or § 161.32, as applicable, of this chapter. The summary must state that it is releasable to the public after registration in accordance with § 152.119.

* * * * *

(f) * * *

(2) An applicant must furnish any data specified in part 158 or part 161 of this chapter, as applicable, of this chapter which are required by the Agency to determine that the product meets the registration standards of FIFRA sec. 3(c)(5) or (7). Each study must comply with:

(i) Section 158.32 of this chapter, with respect to format of data submission.

(ii) Section 158.33 of this chapter, with respect to studies for which a claim of trade secret or confidential business information is made.

(iii) Section 158.34 of this chapter, with respect to flagging for potential adverse effects.

(iv) Section 160.12 of this chapter, with respect to a statement whether studies were conducted in accordance with Good Laboratory Practices of part 160.

* * * * *

■ 5. Revise § 152.85 to read as follows:

§ 152.85 Formulators' exemption.

(a) *Statutory provision.* FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to any pesticide contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another person. This provision is commonly referred to as the formulators' exemption.

(b) *Applicability of the formulators' exemption.* (1) The formulators' exemption applies only to data concerning the purchased product or its ingredients. These data may include, but are not limited to, product chemistry, toxicology, residue chemistry, exposure, environmental fate, and ecological effects.

(2) The data to which the formulators' exemption applies usually will concern the safety of one or more of the product's active ingredients, specifically, those active ingredients which are contained in the purchased product. In general, data for which the required test substance is the technical grade of the active ingredient, the pure active ingredient, the radiolabeled pure active ingredient, or a typical end-use product are eligible for the formulators' exemption.

(3) The formulators' exemption generally does not apply to data on the applicant's product itself, including the

safety or efficacy of the product, unless the composition of the product is identical to the purchased product. In general, data for which the required test substance is the product proposed for registration are not eligible for the formulators' exemption.

(c) *Limitation of the formulators' exemption.* EPA interprets FIFRA section 3(c)(2)(D) as allowing an applicant to use the formulators' exemption with respect to data concerning an ingredient of his product only if:

(1) The application indicates that the ingredient's presence in the product is attributable solely to the purchase from another person of an identified, registered product containing that ingredient and the use of the purchased product in formulating the product; and

(2) The purchased product is a registered manufacturing-use product whose label does not prohibit its use for making an end-use product labeled for any use for which the applicant's product will be labeled; or

(3) The purchased product is a registered end-use product labeled for each use for which the applicant's product will be labeled.

(d) *Claiming eligibility for the exemption.* (1) If the product contains one or more ingredients eligible for the formulators' exemption, the applicant need not comply with the requirements of §§ 152.90 through 152.96 with respect to any data requirement pertaining to such ingredient, provided that he submits to the Agency a certification statement containing the following information (a form for this purpose is available from the Agency):

(i) Identification of the applicant, and of the product by EPA registration number or file symbol.

(ii) Identification of each ingredient in the pesticide that is eligible for the formulators' exemption, and the EPA registration number of the product that is the source of that ingredient.

(iii) A statement that the listed ingredients meet the requirements for the formulators' exemption.

(iv) A statement that the applicant has submitted (either previously or with the current application) a complete, accurate and current Confidential Statement of Formula.

(v) The name, title and signature of the applicant or his authorized representative and the date of signature.

(2) An applicant for amended registration is not required to submit a new formulators' exemption statement, if the current statement in Agency files is complete and accurate.

(e) *Approval of registration.* Notwithstanding FIFRA section 3(c)(2)(D), EPA will not approve an application unless there are available to EPA for its review all data that are necessary to make the required risk/benefit finding under FIFRA section 3(c)(5) or section 3(c)(7).

■ 6. Revise § 152.90(a)(2) to read as follows:

§ 152.90 The selective method.

* * * * *

(a) * * *

(2) If a Registration Standard has not been issued, or if an issued Registration Standard does not cover all data requirements for products containing the active ingredient in question, the applicant must list the applicable requirements as prescribed by 40 CFR part 158 or part 161, as applicable. All required (R) studies, and any studies that could be conditionally required (CR) based upon composition, use pattern, or the results of required studies, are to be listed. The applicant may demonstrate via the data gap procedures in § 152.96 that a conditional requirement need not be satisfied by the submission or citation of data at the time of application.

* * * * *

§ 152.91 [Amended]

■ 7. In § 152.91(b) revise the reference ''40 CFR 158.45'' to read ''40 CFR 158.45 or 40 CFR 161.45''.

■ 8. Revise § 152.97(a)(2)(iii) to read as follows:

§ 152.97 Rights and obligations of data submitters.

(a) * * *

(2) * * *

(iii) For each such active ingredient, the type(s) of study he has previously submitted (corresponding to Guidelines reference numbers given in tables in 40 CFR part 158 or part 161, as applicable), the date of submission, and the EPA registration number, file symbol, or other identifying reference for which it was submitted.

* * * * *

■ 9. Revise § 152.104 to read as follows:

§ 152.104 Completeness of applications.

The applicant is responsible for the accuracy and completeness of all information submitted in connection with the application. The Agency will review each application to determine whether it is complete. An application is incomplete if any pertinent item specified in § 152.50 has not been submitted, or has been incorrectly submitted (for example, data required by part 158, or part 161 of this chapter, as applicable, and not submitted in accordance with the requirements for format, claims of confidential business information, or flagging).

§ 152.107 [Amended]

■ 10. In § 152.107(b)(3) revise the reference ''§ 158.34 of this chapter'' to read ''§ 158.34 or § 161.34 of this chapter''.

■ 11. Revise § 152.112(d) to read as follows:

§ 152.112 Approval of registration under FIFRA sec. 3(c)(5).

* * * * *

(d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted by part 158 or part 161, as applicable, of this chapter for the product.

* * * * *

■ 12. Revise § 152.403(b) to read as follows:

§ 152.403 Definitions of fee categories.

* * * * *

(b) *New biochemical and microbial registration review* means review of an application for registration of a biochemical or microbial pesticide product containing a biochemical or microbial active ingredient not contained in any other pesticide product that is registered under FIFRA at the time the application is made. For purposes of this subpart, the definitions of biochemical and microbial pesticides contained in § 158.2000 and § 158.2100, respectively, shall apply.

* * * * *

PART 156—[AMENDED]

■ 13. The authority citation for part 156 continues to read as follows:

Authority: 7 U.S.C. 136–136y.

§ 156.208 [Amended]

■ 14. In § 156.208(e)(1) revise the reference to ''§ 158.390'' to read ''§ 158.1070 or § 161.390''.

PART 159—[AMENDED]

■ 15. The authority citation for part 159 continues to read as follows:

Authority: 7 U.S.C. 136–136y.

§ 159.156 [Amended]

■ 16. Section 159.156 is amended as follows:

■ a. In paragraph (e) revise the reference to ''§ 158.32 of this chapter'' to read ''§ 158.32 or § 161.32 of this chapter, as applicable''.

■ b. In paragraph (g) revise the reference to ''§ 158.33 of this chapter'' to read ''§ 158.33 or § 161.33 of this chapter, as applicable''.

■ c. In paragraph (h) revise the reference to ''§ 158.34 of this chapter'' to read ''§ 158.34 or § 161.34 of this chapter, as applicable''.

■ 17. Revise § 159.188(a)(2) to read as follows:

§ 159.188 Failure of performance information.

(a) * * *

(2) A study which indicates that the pesticide may not perform in accordance with one or more claims made by the registrant regarding uses intended for control of microorganisms tha may pose a risk to human health, including any of the public health antimicrobials identified in part 161 of this chapter.

* * * * *

PART 160—[AMENDED]

■ 18. The authority citation for part 160 continues to read as follows:

Authority: 7 U.S.C. 136a, 136c, 136d, 136f, 136j, 136v, 136w; 21 U.S.C. 346a, 348, 371, Reorganization Plan No. 3 of 1970.

■ 19. In § 160.3, revise the definition for the term ''Study'' to read as follows:

§ 160.3 Definitions.

* * * * *

Study means any experiment at one of more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance (efficacy studies only as required by 40 CFR 158.400 or 161.640, as applicable), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media. The term ''study''does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility.

* * * * *

PART 168—[AMENDED]

■ 20. The authority citation for part 168 continues to read as follows:

Authority: 7 U.S.C. 136–136y.

■ 21. Section 168.75 is amended by revising the reference in paragraph (b)(4)(ii) to ''§ 158.640 of this chapter'' to read ''§ 158.400 or § 161.640 of this chapter, as applicable'', and by revising paragraph (b)(3)(ii) to read as set follows:

§ 168.75 Procedures for exporting unregistered pesticides—purchaser acknowledgement statements.

* * * * *

(b) * * *

(3) * * *

(ii) An exporter who is also the manufacturer of a U.S. registered pesticide may add new uses to the label of that product for export purposes, without triggering the requirements of section 17(a)(2), as long as the new uses are within the same general use patterns as those for the registered product. The general pesticide use patterns are: terrestrial food crop and terrestrial non-food crop; greenhouse food crop and greenhouse nonfood crop; aquatic food crop and aquatic nonfood crop' indoor use' and forestry use. Adding new uses to the label which change the use pattern, such as changes from nonfood to food use, outdoor to indoor use, or terrestrial to aquatic use, render the product unregistered and subject to the requirements of section 17 for unregistered products. If the new use added to the label is a food or feed use, a tolerance must already be established for the use of that pesticide in or on that commodity.

* * * * *

PART 172—[AMENDED]

■ 22. The Authority citation for part 172 continues to read as follows:

Authority: 7 U.S.C. 136c, 136w. Section 172.4 is also issued under 31 U.S.C. 9701.

■ 23. In § 172.43 revise the definition for ''microbial pesticide'' to read as follows:

§ 172.43 Definitions.

* * * * *

Microbial pesticide means a microbial agent intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, that:

(1) Is a eucaryotic microorganism including, but not limited to, protozoa, algae and fungi;

(2) Is a procaryotic microorganism, including, but not limited to, Eubacteria and Archaebacteria; or

(3) Is a parasitically replicating microscopic element, including, but not limited to, viruses.

* * * * *

§ 172.46 [Amended]

■ 24. In § 172.46(c) introductory text, revise the phrases ''§§ 158.32 and 158.33 of this chapter'' to read ''§§ 158.32 and 158.33 or 161.31 and 161.33 of this chapter''

[FR Doc. E7–20827 Filed 10–25–07; 8:45 am]

BILLING CODE 6560–50–S

Federal Register

Friday,
October 26, 2007

Part III

The President

Presidential Determination No. 2008–2 of October 11, 2007—Waiver and Certification of Statutory Provisions Regarding the Palestine Liberation Organization Office

Presidential Determination No. 2008–3 of October 16, 2007—Provision of U.S. Drug Interdiction Assistance to the Government of Brazil

Presidential Determination No. 2008–4 of October 18, 2007—Presidential Determination With Respect to Foreign Governments' Efforts Regarding Trafficking in Human Persons

Presidential Determination No. 2008–5 of October 19, 2007—Presidential Determination Relating to Assistance for Saudi Arabia

Federal Register
Vol. 72, No. 207
Friday, October 26, 2007

Presidential Documents

Title 3—

The President

Presidential Determination No. 2008–2 of October 11, 2007

Waiver and Certification of Statutory Provisions Regarding the Palestine Liberation Organization Office

Memorandum for the Secretary of State

Pursuant to the authority and conditions contained in section 534(d) of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 2006, Public Law 109–102, as carried forward by the Revised Continuing Appropriations Resolution, 2007, Public Law 110–5, and the Continuing Appropriations Resolution, 2008, Public Law 110–92, I hereby determine and certify that it is important to the national security interests of the United States to waive the provisions of section 1003 of the Anti-Terrorism Act of 1987, Public Law 100–204.

This waiver shall be effective for a period of 6 months. You are hereby authorized and directed to transmit this determination to the Congress and to publish it in the **Federal Register**.

THE WHITE HOUSE,
Washington, October 11, 2007.

[FR Doc. 07–5369
Filed 10–25–07; 8:45 am]
Billing code 4710–10–P

Presidential Documents

Presidential Determination No. 2008–3 of October 16, 2007

Provision of U.S. Drug Interdiction Assistance to the Government of Brazil

Memorandum for the Secretary of State [and] the Secretary of Defense

Pursuant to the authority vested in me by section 1012 of the National Defense Authorization Act for Fiscal Year 1995, as amended (22 U.S.C. 2291–4), I hereby certify, with respect to Brazil, that (1) interdiction of aircraft reasonably suspected to be primarily engaged in illicit drug trafficking in that country's airspace is necessary because of the extraordinary threat posed by illicit drug trafficking to the national security of that country; and (2) that country has appropriate procedures in place to protect against innocent loss of life in the air and on the ground in connection with such interdiction, which shall at a minimum include effective means to identify and warn an aircraft before the use of force is directed against the aircraft.

The Secretary of State is authorized and directed to publish this determination in the **Federal Register** and to notify the Congress of this determination.

THE WHITE HOUSE,
Washington, October 16, 2007.

[FR Doc. 07–5370
Filed 10–25–07; 8:45 am]
Billing code 4710–10–P

Presidential Documents

Presidential Determination No. 2008–4 of October 18, 2007

Presidential Determination With Respect to Foreign Governments' Efforts Regarding Trafficking in Persons

Memorandum for the Secretary of State

Consistent with section 110 of the Trafficking Victims Protection Act of 2000 (Division A of Public Law 106–386), as amended, (the ''Act''), I hereby:

Make the determination provided in section 110(d)(1)(A)(i) of the Act, with respect to Burma, Syria, and Venezuela not to provide certain funding for those countries' governments for Fiscal Year 2008, until such government complies with the minimum standards or makes significant efforts to bring itself into compliance, as may be determined by the Secretary of State in a report to the Congress pursuant to section 110(b) of the Act;

Make the determination provided in section 110(d)(1)(A)(ii) of the Act, with respect to Cuba, the Democratic People's Republic of Korea (DPRK), and Iran not to provide certain funding for those countries' governments for Fiscal Year 2008, until such government complies with the minimum standards or makes significant efforts to bring itself into compliance, as may be determined by the Secretary of State in a report to the Congress pursuant to section 110(b) of the Act;

Make the determination provided in section 110(d)(3) of the Act, concerning the determination of the Secretary of State with respect to Equatorial Guinea and Kuwait.

Determine, consistent with section 110(d)(4) of the Act, with respect to Algeria, that provision to Algeria of all programs, projects, or activities of assistance described in sections 110(d)(1)(A)(i) and 110(d)(1)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Bahrain, that provision to Bahrain of all programs, projects, or activities of assistance described in sections 110(d)(1)(A)(i) and 110(d)(1)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to DPRK, that funding for educational and cultural exchange programs described in section 110(d)(1)(A)(ii) of the Act that are aimed at improving U.S.-DPRK relations would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Iran, that funding for educational and cultural exchange programs described in section 110(d)(1)(A)(ii) of the Act that include educators and municipal leaders would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Malaysia, that provision to Malaysia of all programs, projects, or activities of assistance described in sections 110(d)(1)(A)(i) and 110(d)(1)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Oman, that provision to Oman of all programs, projects, or activities of assistance described in sections 110(d)(1)(A)(i) and 110(d)(1)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Qatar, that provision to Qatar of all programs, projects, or activities of assistance described in sections 110(d)(1)(A)(i) and 110(d)(1)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Saudi Arabia, that provision to Saudi Arabia of all programs, projects, or activities of assistance described in sections 110(d)(1)(A)(i) and 110(d)(1)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Sudan, that provision to Sudan of all programs, projects, or activities of assistance described in sections 110(d)(1)(A)(i) and 110(d)(1)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Syria, for all programs, projects, or activities of assistance for victims of trafficking in persons or to combat such trafficking, that provision to Syria of the assistance described in section 110(d)(1)(A)(i) of the Act for such programs, projects, or activities would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Uzbekistan, that provision to Uzbekistan of all programs, projects, or activities of assistance described in sections 110(d)(1)(A)(i) and 110(d)(1)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Venezuela, for all programs, projects, or activities of assistance for victims of trafficking in persons or to combat such trafficking, or for strengthening democracy or good governance, or for public diplomacy, that provision to Venezuela of the assistance described in sections 110(d)(1)(A)(i) and 110(d)(1)(B) of the Act for such programs, projects, or activities would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, that assistance to Venezuela described in section 110(d)(1)(B) of the Act that:

(1) is a regional program, project, or activity under which the total benefit to Venezuela does not exceed 10 percent of the total value of such program, project, or activity; or

(2) has as its primary objective the addressing of basic human needs, as defined by the Department of the Treasury with respect to other, existing legislative mandates concerning U.S. participation in the multilateral development banks; or

(3) is complementary to or has similar policy objectives to programs being implemented bilaterally by the United States Government; or

(4) has as its primary objective the improvement of the country's legal system, including in areas that impact the country's ability to investigate and prosecute trafficking cases or otherwise improve implementation of a country's anti-trafficking policy, regulations, or legislation; or

(5) is engaging a government, international organization, or civil society organization, and that seeks as its primary objective(s) to: (a) increase efforts to investigate and prosecute trafficking in persons crimes; (b) increase protection for victims of trafficking through better screening, identification, rescue/removal, aftercare (shelter, counseling) training and reintegration; or (c) expand prevention efforts through education and awareness campaigns highlighting the dangers of trafficking or training and economic empowerment of populations clearly at risk of falling victim to trafficking would promote the purposes of the Act or is otherwise in the national interest of the United States.

The certification required by section 110(e) of the Act is provided herewith.

You are hereby authorized and directed to submit this determination to the Congress, and to publish it in the **Federal Register**.

THE WHITE HOUSE,
Washington, October 18, 2007.

[FR Doc. 07–5371
Filed 10–25–07; 8:45 am]
Billing code 4710–10–P

Presidential Documents

Presidential Determination No. 2008–5 of October 19, 2007

Presidential Determination Relating to Assistance for Saudi Arabia

Memorandum for the Secretary of State

Pursuant to the authority vested in me by the Constitution and the laws of the United States, including section 582 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 2006 (Public Law 109–102), and that section as carried forward by the Revised Continuing Appropriations Resolution, 2007 (Public Law 110–5), and the Continuing Appropriations Resolution, 2008 (Public Law 110–92), I hereby certify that Saudi Arabia is cooperating with efforts to combat international terrorism and that the proposed assistance will help facilitate that effort, and hereby waive the application of such sections.

You are authorized and directed to report this certification to the Congress and publish it in the **Federal Register**.

THE WHITE HOUSE,
Washington, October 19, 2007.

[FR Doc. 07–5372
Filed 10–25–07; 8:45 am]
Billing code 4710–10–P

Federal Register

Friday,
October 26, 2007

Part IV

The President

Notice of October 24, 2007—Continuation of the National Emergency With Respect to the Situation in or in Relation to the Democratic Republic of the Congo

Federal Register
Vol. 72, No. 207
Friday, October 26, 2007

Presidential Documents

Title 3—

The President

Notice of October 24, 2007

Continuation of the National Emergency With Respect to the Situation in or in Relation to the Democratic Republic of the Congo

On October 27, 2006, by Executive Order 13413, I declared a national emergency with respect to the situation in or in relation to the Democratic Republic of the Congo and, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706), ordered related measures blocking the property of certain persons contributing to the conflict in that country. I took this action to deal with the unusual and extraordinary threat to the foreign policy of the United States constituted by the situation in or in relation to the Democratic Republic of the Congo, which has been marked by widespread violence and atrocities that continue to threaten regional stability and was addressed by the United Nations Security Council in Resolution 1596 of April 18, 2005, Resolution 1649 of December 21, 2005, and Resolution 1698 of July 31, 2006.

Because this situation continues to pose an unusual and extraordinary threat to the foreign policy of the United States, the national emergency declared on October 27, 2006, and the measures adopted on that date to deal with that emergency, must continue in effect beyond October 27, 2007. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13413.

This notice shall be published in the **Federal Register** and transmitted to the Congress.

THE WHITE HOUSE,
October 24, 2007.

[FR Doc. 07–5375
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Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
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FEDERAL REGISTER PAGES AND DATE, OCTOBER

55655–56008 1
56009–56240 2
56241–56616 3
56617–56882 4
56883–57194 5
57195–57482 9
57483–57838 10
57839–58002 11
58003–58242 12
58243–58468 15
58469–58752 16
58753–58990 17
58991–59152 18
59153–59474 19
59475–59938 22
59939–60226 23
60227–60532 24
60533–60758 25
60759–61046 26

CFR PARTS AFFECTED DURING OCTOBER

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:
5030 (See EO 13449) 60531
6641 (See Proclamation 8180) 56171
8180 56171
8181 56613
8182 56615
8183 56879
8184 56881
8185 57477
8186 57479
8187 57481
8188 57483
8189 58467
8190 58749
8191 58751
8192 60527
8193 60529
8194 60757

Executive Orders:
11145 (Continued by EO 13446) 56175
11183 (Continued by EO 13446) 56175
11287 (Continued by EO 13446) 56175
12131 (Continued by EO 13446) 56175
12196 (Continued by EO 13446) 56175
12216 (Continued by EO 13446) 56175
12367 (Continued by EO 13446) 56175
12382 (Continued by EO 13446) 56175
12473 (See EO 13447) 56179
12905 (Continued by EO 13446) 56175
12978 (See Notice of October 18, 2007) 59473
12994 (Amended by EO 13446) 56175
13047 (See EO 13448) 60223
13226 (Continued by EO 13446) 56175
13231 (Continued by EO 13446) 56175
13237 (Continued by EO 13446) 56175
13256 (Continued by EO 13446) 56175
13262 (See EO 13447) 56179
13265 (Continued by EO 13446) 56175
13270 (Continued by EO 13446) 56175
13310 (See EO 13448) 60223
13369 (Revoked by EO 13446) 56175
13379 (See EO 13446) 56175
13385 (Superseded in part by EO 13446) 56175
13386 (See EO 13446) 56175
13413 (See Notice of October 24, 2007) 61045
13449 60531
13445 56165
13446 56175
13447 56179
13448 60223
13449 60531

Administrative Orders:
Notices:
Notice of October 18, 2007 59473
Notice of October 24, 2007 61045
Memorandums:
Memorandum of September 28, 2007 56871
Presidential Determinations:
No. 2007-34 of September 28, 2007 56873
No. 2007-35 of September 28, 2007 56875
No. 2008-1 of October 2, 2007 58991
No. 2008-2 of October 11, 2007 61033
No. 2008-3 of October 16, 2007 61035
No. 2008-4 of October 18, 2007 61037
No. 2008-5 of October 19, 2007 61041

5 CFR

894 58243
1201 56883
1210 56883
1215 56883
1830 56617
2634 56241
2638 56241

Proposed Rules:
352 56019
630 58263

7 CFR

28 56242
205 58469
301 ..... 57195, 60533, 60759

319.....60537
924.....58003
984.....57839
989.....59153
1206.....60541

Proposed Rules:
6.....56677
Ch. VIII.....56945
319.....60790
925.....60588
944.....60588
962.....56678

8 CFR

103.....56832
204.....56832
213a.....56832
299.....56832
322.....56832

9 CFR

93.....58375
94.....58375
95.....58375
96.....58375

10 CFR

Ch. I.....59157
2.....57416
20.....55864, 59162
30.....55864, 58473
31.....55864, 58473
32.....55864, 58473
33.....55864
35.....55864
50.....55864, 57416
51.....57416
52.....57416
61.....55864
62.....55864
72.....55864, 60543, 60760
100.....57416
110.....55864
150.....55864, 58473
170.....55864
171.....55864
430.....59906
431.....58190
609.....60116

Proposed Rules:
35.....60285
50.....56275
52.....56287
63.....60288
72.....60589
430.....57254, 59039

11 CFR

113.....56245

Proposed Rules:
100.....58028, 59953
104.....58028
113.....59953
114.....58028
9004.....59953
9034.....59953

12 CFR

201.....56889
204.....55655
218.....56514
344.....60547
701.....56247
711.....58248

Proposed Rules:
16.....59039
233.....56680
327.....58743

13 CFR

Proposed Rules:
124.....57889

14 CFR

1.....59598
11.....59598
23.....59939
25.....57842, 57844
33.....58972
39.....55657, 56254, 56256, 56258, 56262, 56618, 56890, 56891, 57195, 57848, 57850, 57854, 58005, 58007, 58489, 58491, 58492, 58495, 58497, 58499, 58502, 58504, 58753, 58755, 59475, 60227, 60228, 60231, 60233, 60236, 60238, 60240, 60244, 60760, 60762
60.....59598
71.....57485, 57486, 58993, 60247, 60764
91.....57196
95.....56009
97.....56266, 56894, 58507, 58509
119.....57196
121.....57196, 59598
135.....57196

Proposed Rules:
25.....58560
39.....56700, 56945, 57502, 57890, 57892, 57894, 57896, 58028, 58267, 58763, 58766, 58768, 58770, 58773, 58774, 58777, 59225, 59227, 59229, 59967, 59969, 60291, 60293, 60591, 60593, 60595, 60599, 60600, 60604, 60606, 60790
60.....59600
71.....57898, 58561, 58563, 58565, 58566, 58567, 58569
73.....59971
91.....56947

15 CFR

19.....57198
21.....57198
22.....57198
740.....58757, 60248
744.....60248
748.....56010, 59164, 60408

Proposed Rules:
740.....59231
742.....59231
744.....59231
748.....59231
754.....59231
764.....59231
772.....59231

16 CFR

1630.....60765
1631.....60765

17 CFR

18.....60767
240.....56514, 56562
247.....56514

18 CFR

157.....59939
1301.....60547

Proposed Rules:
410.....57255
806.....55711
808.....55711

19 CFR

Ch. I.....59166
10.....58511
24.....58511
102.....58511
122.....59943
162.....58511
163.....58511
178.....58511

20 CFR

404.....59398
416.....59398

21 CFR

314.....58993
516.....57199
520.....60550, 60551
522.....56896
556.....56896, 57199
558.....56896, 60551
600.....59000
880.....59175

Proposed Rules:
15.....59973
600.....59041
870.....56702
1314.....55712

22 CFR

171.....57857

24 CFR

203.....56002, 56156
982.....59936
1000.....59003
3280.....59338
3285.....59338

Proposed Rules:
5.....58448

25 CFR

Proposed Rules:
502.....59044, 60482, 60483
522.....59044
542.....60495
543.....60495
546.....60483
547.....60508
559.....59044
573.....59044

26 CFR

1.....56619, 57487, 58375, 58758, 60250, 60552
602.....58375

Proposed Rules:
1.....57503, 58781, 58787
301.....56704

28 CFR

Proposed Rules:
16.....56704

29 CFR

2550.....60452
4022.....58249
4044.....58249

Proposed Rules:
2702.....58790
4003.....59050

30 CFR

914.....59005
917.....59477
926.....57822
938.....56619
946.....59009

Proposed Rules:
250.....56442
253.....56442
254.....56442
256.....56442
780.....57504
784.....57504
816.....57504
817.....57504
944.....59489

31 CFR

92.....60772
203.....59177
285.....59480

Proposed Rules:
132.....56680
800.....57900

32 CFR

213.....56011
752.....56267

Proposed Rules:
212.....56021
217.....59053

33 CFR

100.....60558
117.....56013, 56898, 57487, 57858, 58250, 58758, 58759, 59012, 59013
165.....56014, 56898, 57200, 57858, 57861, 57863, 58522, 59944, 60559, 60779

Proposed Rules:
110.....57901, 59491
117.....56025, 57904
165.....56308, 56972
169.....56600
175.....59064

34 CFR

Proposed Rules:
Ch. VI.....59494

36 CFR

223.....59187

Proposed Rules:
Ch. I.....58030
223.....59496
261.....59979

37 CFR

1.....57863

Proposed Rules:
2.....60609
381.....57101

38 CFR

14.....58009

Proposed Rules:
5.....56136

39 CFR

111.....56901, 57488
601.....58251

Proposed Rules:
111.....57505, 57506, 57507

121.....58946
122.....58946

40 CFR

9.....56903, 60934
51.....55657, 59190
52 .....55659, 55664, 55666, 56268, 56623, 56911, 56914, 57202, 57207, 57209, 57864, 58013, 58016, 58523, 58528, 58535, 58538, 58542, 58546, 58759, 59014, 59207, 59210, 59213, 59480, 60781, 60783
55.....59947, 60251
59.....57215
60.....59190, 60561
61.....60561
62.....59017
63.....60561
70.....58535
72.....59190
78.....59190
80.....60570
81 .....57207, 58538, 59210, 59213
82.....56628
96.....59190
97 .....55657, 55666, 56914, 57209, 58542, 58546, 59190, 59480
141.....57782
142.....57782
152.....61025
156.....61025
158 .....60251, 60934, 60988
159.....61025
160.....61025
161.....60251
168.....61025
172.....61025
180 .....57489, 57492, 60255, 60261, 60266
300.....60786
721.....56903, 57222
750.....57235
761.....57235

Proposed Rules:

50.....58030
51.....55717, 59065
52 .....55723, 56312, 56706, 56707, 56974, 56975, 57257, 57907, 58031, 58570, 58571, 59065, 59066, 59506, 60296, 60793
63.....59067
70.....58571, 59065
71.....59065
81 .....56312, 58572, 58577, 60296
97.....58571, 59506
112.....58378
180.....56325
271.....57258

42 CFR

411.....57634
412.....57634
413.....57634
418.....55672
482.....60787
489.....57634
1001.....56632

Proposed Rules:

71.....55729

43 CFR

Proposed Rules:

2.....60611
10.....58582

44 CFR

64.....58020
65.....57241
67 .....56920, 57245, 58553
206.....57869
207.....57869

Proposed Rules:

67 .....56975, 58590, 58598, 58599, 58615

46 CFR

67.....58762
515.....56272

47 CFR

1.....56015
12.....57879
22.....56015
24.....56015
25.....60272
27.....56015
53.....58021
64.....58021
73.....59488
76.....56645
90 .....56015, 56923, 57888
101.....55673

Proposed Rules:

73 .....59507, 59508, 59509, 59510

48 CFR

Proposed Rules:

1516.....56708
1533.....56708
1552.....56708

49 CFR

105.....55678
106.....55678
107.....55678
110.....55678
130.....55678
171.....55678
172.....55678, 59146
173.....55678
174.....55678
175.....55678
176.....55678
178.....55678, 59146
179.....55678
180.....55678
222.....59019
229.....59216
365.....55697
369.....55697
381.....55697
382.....55697
383.....55697
384.....55697
385.....55697
386.....55697
387.....55697
388.....55697
389.....55697
390.....55697
391.....55697
392.....55697
393.....55697
395.....55697
397.....55697
512.....59434
571.....57450

Proposed Rules:

379.....60614
381.....60614
385.....60614
390.....60614
395.....60614
541.....58268
565.....56027
571 .....56713, 57260, 57459
1540.....60307
1544.....60307
1560.....60307

50 CFR

16.....59019
17.....60068, 60410
20.....58452
21.....56926
229 .....57104, 59035, 60280, 60583
635.....56929, 57104
648 .....55704, 57104, 57500, 59224, 59951, 60282, 60585
660 .....55706, 55707, 55708, 55709, 56664, 58258, 60586
665.....58259
679 .....56016, 56017, 56273, 56274, 56933, 56934, 57252, 57501, 57888, 58261, 58559, 59037, 59038, 59952, 60283, 60586
697.....56935

Proposed Rules:

17 .....56979, 57273, 57276, 57278, 57511, 57740, 58618, 58793, 59979, 59983
26.....58982
92.....58274
216.....58279
622 .....58031, 59989, 60794
635 .....55729, 56036, 56330
648.....58280, 58622

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 OCTOBER 26, 2007

AGRICULTURE DEPARTMENT
Agricultural Marketing Service
Mango promotion, research, and information order; term of office provision; published 10-25-07

AGRICULTURE DEPARTMENT
Animal and Plant Health Inspection Service
Plant-related quarantine, domestic:
Oriental fruit fly; published 10-26-07

CONSUMER PRODUCT SAFETY COMMISSION
Flammable Fabrics Act:
Carpets and rugs; flammability standards; published 10-26-07

ENVIRONMENTAL PROTECTION AGENCY
Superfund program:
National oil and hazardous substances contingency plan priorities list; published 8-27-07
Superfund:
National oil and hazardous substances contingency plan priorities list; published 10-26-07

FEDERAL COMMUNICATIONS COMMISSION
Television broadcasting:
Advanced television (ATV) systems—
Digital television transition; DTV table of allotments; published 9-26-07

HEALTH AND HUMAN SERVICES DEPARTMENT
Centers for Medicare & Medicaid Services
Medicare:
Organ transplant centers; hospital participation conditions; approval and re-approval requirements
Correction; published 10-26-07

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Airbus; published 9-21-07
Boeing; published 9-21-07
DG Flugzeugbau GmbH; published 9-21-07
McDonnell Douglas; published 9-21-07
SICMA Aero Seat; published 9-21-07
Airworthiness standards:
Special conditions—
Boeing Model 787-8 airplane; published 9-26-07
Boeing Model 787-8 airplane; published 9-26-07

RULES GOING INTO EFFECT OCTOBER 27, 2007

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Marine mammals:
Commercial fishing authorizations—
Atlantic Large Whale Take Reduction Plan; published 10-25-07

HOMELAND SECURITY DEPARTMENT
Coast Guard
Drawbridge operations:
Louisiana; published 9-25-07

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT
Animal and Plant Health Inspection Service
Agricultural Bioterrorism Protection Act of 2002; implementation:
Select agent and toxin list; biennial review and republication; comments due by 10-29-07; published 8-28-07 [FR E7-17039]

AGRICULTURE DEPARTMENT
Grain Inspection, Packers and Stockyards Administration
Practice and procedure:
Packers and Stockyards Act; poultry contracts; initiation, performance, and termination; comments due by 10-30-07; published 8-1-07 [FR E7-14924]

AGRICULTURE DEPARTMENT
Rural Utilities Service
Materials and construction; electric standards and specifications:
Primary underground power cable; comments due by 10-29-07; published 8-30-07 [FR E7-17194]

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
Atlantic highly migratory species—
Atlantic bluefin tuna; comments due by 11-1-07; published 10-2-07 [FR E7-19421]
Atlantic commercial shark management measures; comments due by 10-31-07; published 10-1-07 [FR E7-19378]
Atlantic shark; comments due by 11-2-07; published 10-3-07 [FR E7-19544]
Northeastern United States fisheries—
Northeast multispecies; comments due by 10-31-07; published 10-16-07 [FR E7-20386]
West Coast States and Western Pacific fisheries—
Coastal pelagic species; comments due by 10-29-07; published 9-28-07 [FR E7-19252]

DEFENSE DEPARTMENT
Defense Acquisition Regulations System
Acquisition regulations:
Carriage vessel overhaul, repair and maintenance; comments due by 10-29-07; published 8-28-07 [FR E7-17037]

ENVIRONMENTAL PROTECTION AGENCY
Air programs; approval and promulgation; State plans for designated facilities and pollutants:
Missouri; comments due by 10-29-07; published 9-27-07 [FR E7-19120]
Air quality implementation plans:
Preparation, adoption, and submittal—
Volatile organic compounds; definition revised; comments due by 10-31-07; published 10-1-07 [FR E7-19324]
Air quality implementation plans; approval and promulgation; various States
New York; comments due by 10-31-07; published 10-1-07 [FR E7-19346]
Air quality implementation plans; approval and promulgation; various States; air quality planning purposes; designation of areas:
North Carolina; comments due by 11-2-07; published 10-3-07 [FR E7-19513]
Air quality implementation plans; approval and promulgation; various States:
Ohio; comments due by 10-29-07; published 9-27-07 [FR E7-18894]
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Dibasic esters; comments due by 10-29-07; published 8-29-07 [FR E7-17109]
Flusilazole; comments due by 10-29-07; published 8-29-07 [FR E7-17110]
Flutriafol; comments due by 10-29-07; published 8-29-07 [FR E7-17112]
Propylene oxide; comments due by 10-29-07; published 8-29-07 [FR E7-17010]
Spinosad; comments due by 10-29-07; published 8-29-07 [FR E7-16897]

FARM CREDIT ADMINISTRATION
Farm credit system:
Federal Agriculture Mortgage Corporation funding and fiscal affairs—
Risk-based capital requirements; comments due by 10-29-07; published 9-13-07 [FR E7-18014]

FEDERAL COMMUNICATIONS COMMISSION
Common carrier services:
Commercial mobile radio service providers; roaming obligations reexamination; comments due by 10-29-07; published 8-30-07 [FR E7-17123]

HEALTH AND HUMAN SERVICES DEPARTMENT
Centers for Medicare & Medicaid Services
Medicaid:
Outpatient clinic and hospital facility services; definitions and payment limits; comments due by 10-29-07; published 9-28-07 [FR E7-19154]
Medicare and Medicaid:
Ambulatory surgical centers; coverage conditions; comments due by 10-30-

07; published 8-31-07 [FR 07-04148]

Medicare:

Home health prospective payment system; 2008 CY refinement and rate update; comments due by 10-29-07; published 8-29-07 [FR 07-04184]

HEALTH AND HUMAN SERVICES DEPARTMENT

Food and Drug Administration

Biological products:

Blood, blood components, and source plasma; requirements; comments due by 10-30-07; published 8-16-07 [FR E7-15943]

Blood, blood components, and source plasma; requirements—

Correction; comments due by 10-30-07; published 9-24-07 [FR E7-18802]

HEALTH AND HUMAN SERVICES DEPARTMENT

Quarantine, inspection, and licensing:

Select agents and toxins; possession, use, and transfer; comments due by 10-29-07; published 8-28-07 [FR 07-04233]

INTERIOR DEPARTMENT

Fish and Wildlife Service

Endangered and threatened species:

Critical habitat designations—

Monterey spineflower; comments due by 10-31-07; published 10-16-07 [FR E7-20241]

Findings on petitions, etc.—

Gunnison's prairie dog; comments due by 10-29-07; published 8-28-07 [FR E7-16941]

MILLENNIUM CHALLENGE CORPORATION

Freedom of Information Act; implementation; comments due by 10-29-07; published 8-28-07 [FR E7-16143]

NATIONAL CREDIT UNION ADMINISTRATION

Credit unions:

Federal and corporate credit unions; permissible foreign currency investments; comments due by 10-30-07; published 8-1-07 [FR E7-14849]

SECURITIES AND EXCHANGE COMMISSION

Investment advisers:

Broker-dealers; Interpretive rule provisions; comments due by 11-2-07; published 9-28-07 [FR E7-19269]

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

Airbus; comments due by 10-29-07; published 9-28-07 [FR E7-19258]

Alexandria Aircraft, LLC; comments due by 10-30-07; published 8-31-07 [FR E7-17289]

ATR; comments due by 10-29-07; published 9-28-07 [FR E7-19201]

Airworthiness Directives:

BAE Systems (Operations) Ltd.; comments due by 10-29-07; published 9-28-07 [FR E7-19197]

Airworthiness directives:

Boeing; comments due by 10-29-07; published 8-28-07 [FR E7-16909]

General Electric Co.; comments due by 10-29-07; published 8-28-07 [FR E7-16554]

Saab; comments due by 10-29-07; published 9-28-07 [FR E7-19202]

Class E airspace; comments due by 11-2-07; published 9-18-07 [FR E7-18332]

Meetings:

RTCA Inc.; comments due by 10-29-07; published 10-29-07 [FR 07-05320]

TRANSPORTATION DEPARTMENT

Federal Transit Administration

Major capital investment projects:

New Starts Program and proposed Small Starts program category; comments due by 11-1-07; published 8-3-07 [FR E7-14285]

TREASURY DEPARTMENT

Internal Revenue Service

Estate and gift taxes:

Generation-skipping transfer tax purposes; severance of trust; comments due by 10-31-07; published 8-2-07 [FR E7-14850]

Income taxes:

Variable annuity, endowment, and life insurance contracts; diversification requirements; comments due by 10-29-07; published 7-31-07 [FR E7-14620]

Income taxes:

Losses sustained from abandoned securities; comments due by 10-29-07; published 7-30-07 [FR E7-14616]

Type III supporting organizations that are not functionally integrated; payout requirements; comments due by 10-31-07; published 8-2-07 [FR E7-14925]

TREASURY DEPARTMENT

Alcohol and Tobacco Tax and Trade Bureau

Alcoholic beverages:

Wines, distilled spirits, and malt beverages; labeling and advertising—

Alcohol content statement; comments due by 10-29-07; published 7-31-07 [FR E7-14774]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

H.R. 1124/P.L. 110–97

To extend the District of Columbia College Access Act of 1999. (Oct. 24, 2007; 121 Stat. 1013)

H.R. 2467/P.L. 110–98

To designate the facility of the United States Postal Service located at 69 Montgomery Street in Jersey City, New Jersey, as the ''Frank J. Guarini Post Office Building''. (Oct. 24, 2007; 121 Stat. 1014)

H.R. 2587/P.L. 110–99

To designate the facility of the United States Postal Service located at 555 South 3rd Street Lobby in Memphis, Tennessee, as the ''Kenneth T. Whalum, Sr. Post Office Building''. (Oct. 24, 2007; 121 Stat. 1015)

H.R. 2654/P.L. 110–100

To designate the facility of the United States Postal Service located at 202 South Dumont Avenue in Woonsocket, South Dakota, as the ''Eleanor McGovern Post Office Building''. (Oct. 24, 2007; 121 Stat. 1016)

H.R. 2765/P.L. 110–101

To designate the facility of the United States Postal Service located at 44 North Main Street in Hughesville, Pennsylvania, as the ''Master Sergeant Sean Michael Thomas Post Office''. (Oct. 24, 2007; 121 Stat. 1017)

H.R. 2778/P.L. 110–102

To designate the facility of the United States Postal Service located at 3 Quaker Ridge Road in New Rochelle, New York, as the ''Robert Merrill Postal Station''. (Oct. 24, 2007; 121 Stat. 1018)

H.R. 2825/P.L. 110–103

To designate the facility of the United States Postal Service located at 326 South Main Street in Princeton, Illinois, as the ''Owen Lovejoy Princeton Post Office Building''. (Oct. 24, 2007; 121 Stat. 1019)

H.R. 3052/P.L. 110–104

To designate the facility of the United States Postal Service located at 954 Wheeling Avenue in Cambridge, Ohio, as the ''John Herschel Glenn, Jr. Post Office Building''. (Oct. 24, 2007; 121 Stat. 1020)

H.R. 3106/P.L. 110–105

To designate the facility of the United States Postal Service located at 805 Main Street in Ferdinand, Indiana, as the ''Staff Sergeant David L. Nord Post Office''. (Oct. 24, 2007; 121 Stat. 1021)

H.R. 995/P.L. 110–106

To amend Public Law 106-348 to extend the authorization for establishing a memorial in the District of Columbia or its environs to honor veterans who became disabled while serving in the Armed Forces of the United States. (Oct. 25, 2007; 121 Stat. 1022)

Last List October 17, 2007

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