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Approved: November 20, 2008.

**M. Robb Hyde,**

Commander, JAGC, U.S. Navy, Deputy Assistant Judge Advocate, General (Admiralty and Maritime Law).

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**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Chapter I**

[EPA-HQ-OPP-2008-0247; FRL-8146-6]

**Pesticide Regulations; Technical Amendments**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA has reviewed its pesticide regulations contained in 40 CFR Parts 150-180, and is making technical changes in a number of areas. These technical changes will correct errors and cross-references, improve presentation and format, and conform the regulations to current CFR practice. These changes have no substantive impact on any requirements. As such, notice and public comment procedures are unnecessary, and EPA finds that this constitutes good cause under the Administrative Procedure Act.

**DATES:** This final rule is effective February 10, 2009.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0247. 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 website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [www.regulations.gov](http://www.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 Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One

Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:**

Kathryn Boyle, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6304; fax number: (703) 305-5884; e-mail address: [boyle.kathryn@epa.gov](mailto:boyle.kathryn@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. Does this Action Apply to Me?**

You may be potentially affected by this action if you produce or register pesticide products, or petition the Agency to establish or modify a pesticide tolerance. Potentially affected entities may include, but are not limited to Pesticide Producers (NAICS 32532), e.g., pesticide manufacturers or formulators of pesticide products or importers of pesticide products.

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

**II. Background**

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), the Agency regulates the sale, distribution and use of pesticides. EPA regulations covering activities under these statutes are contained in 40 CFR parts 150 - 180. Many of these regulations were promulgated or last revised in the 1970s and 1980s and have not been significantly updated.

Over the past year, EPA has conducted a detailed review of its pesticide regulations, contained in 40 CFR parts 150 - 180. EPA believes that improvements in these regulations are warranted. Today's final rule makes "housekeeping" or non-substantive technical changes to a series of regulations. Future rulemakings implementing substantive changes will

be issued as proposed rules with opportunity for comment. The types of changes being made today involve error correction, conforming changes, and general non-substantive improvements in presentation and format.

**III. Today's final rule**

In today's final rule EPA is making the following key types of changes to the regulations in 40 CFR parts 150 - 180.

1. EPA is removing compliance and effective dates that have passed. These involve certain provisions concerning:

a. Data compensation (part 152, subpart E);

b. Worker protection interim provisions and exceptions (part 170).

2. EPA is removing unnecessary or obsolete references, including:

a. References to the Pesticide Assessment Guidelines that are not needed in regulatory text (part 172);

b. Definitions related solely to plant-incorporated protectants that are not used in the regulatory text of part 152. These definitions are duplicative of definitions in part 174.

c. Reference in § 180.34 to the certification of usefulness, a provision eliminated by the Food Quality Protection Act (FQPA) in 1996.

3. EPA is removing most references to section 409 of the FFDCA. Prior to 1996, EPA established tolerances for raw agricultural commodities under section 408 and food additive regulations for certain pesticide residues in processed foods under section 409, which pertains to food additives. As part of the FQPA, Congress combined EPA's authority to regulate all pesticide chemical residues in food under section 408 of the FFDCA (leaving the Food and Drug Administration the sole authority under section 409 to regulate food additives). As it no longer has any regulatory authority under section 409, EPA is eliminating most references to FFDCA section 409 from its regulations. Those retained are needed for continued enforcement of pre-FQPA provisions.

4. EPA is correcting other statutory and regulatory cross-references.

a. EPA is correcting the references to data compensation provisions in FIFRA sec. 3(c)(1)(D), which is now 3(c)(1)(F).

b. EPA is correcting the references to FIFRA sec. 4, which is now FIFRA sec. 11.

c. EPA is correcting the regulatory cross-references from § 156.10(h) to § 156.62 and § 162.11 to part 154. These regulations were restructured a number of years ago, but the cross-references were not.

5. EPA is correcting part 155, subpart C, Registration Review Procedures, to include the mandatory 15-year

registration review and minor changes to docket procedures required under the Pesticide Regulatory Improvement Renewal Act.

6. EPA is updating organizational and docket references in the regulations. For example, EPA is revising a reference to the U.S. Bureau of Mines to refer to the National Institute for Occupational Safety and Health. EPA is revising the URL for the location of EPA's electronic dockets to *www.regulations.gov*.

7. EPA is revising the regulations to conform with current CFR practice.

a. EPA is revising the structure used to present definitions. Current CFR practice is to list definitions alphabetically without numeric or alpha paragraph designations. EPA is revising various definitions sections to provide for greater consistency in presentation by removing numeric and alpha paragraph designations from parts 154, 157, 162, 166, and 172. In addition, EPA is standardizing the introductory material and, in a few cases, revising a definition from "term includes" or "term refers to" to "term means." In each instance where EPA is making this revision the existing definition contains language that makes the definition all-inclusive, so that the term "includes" in actuality means "means."

b. EPA is removing the topic headings in part 180, which are no longer used in regulations.

8. EPA is reformatting certain material without substantive change for greater clarity and understanding.

a. EPA is restructuring the opening paragraphs of § 152.1 and § 160.1

b. EPA is revising certain table titles in part 158 to clearly identify experimental use permit versus registration data requirements.

9. EPA is revising section titles to reflect statutory language. Specifically, EPA is revising the titles of § 152.10 and § 152.20 to accurately reflect the underlying statutory language.

#### IV. Good Cause Exemption

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 there is good cause for issuing today's rule final without prior proposal and opportunity for comment because notice and public comment are unnecessary. EPA is making only technical changes that have no substantive effect on any requirement, while improving the

clarity and usefulness of its regulations. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

#### V. FIFRA Review Requirements

In accordance with FIFRA sec. 25(a), a draft of this final rule was submitted to the Secretary of Agriculture, the FIFRA SAP, and appropriate Congressional Committees. The FIFRA SAP and the Secretary of Agriculture waived review of the final rule.

#### VI. Statutory and Executive Order Reviews

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, nor does this rule contain any information collections subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

Because the Agency has made a "good cause" finding that this action is not subject to notice-and-comment requirements under the APA or any other statute (see Unit IV.), it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does this action significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA.

This rule 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, entitled *Federalism* (64 FR 43255, August 10, 1999), nor will this rule have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000).

This rule does not require any special considerations, 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). Nor will this rule have any effect on energy supply, distribution or use as described in Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply,*

*Distribution, or Use* (66 FR 28355, May 22, 2001).

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, Public Law 104-113, section 12(d) (15 U.S.C. 272 note). The rule also does not involve special consideration of environmental justice related issues under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (55 FR 7629, February 16, 1994).

#### VII. 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 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

##### 40 CFR Parts 152 and 154

Environmental protection, Administrative practice and procedure, Pesticides and pest, Reporting and recordkeeping requirements.

##### 40 CFR Part 155

Environmental protection, Administrative practice and procedure, Confidential business information, Pesticides and pest, Reporting and recordkeeping requirements.

##### 40 CFR Part 156

Environmental protection, Administrative practice and procedure, labeling, Pesticides and pest, Reporting and recordkeeping requirements.

##### 40 CFR Part 157

Environmental protection, Administrative practice and procedure, Infants and children, Packaging and containers, Pesticides and pest, Reporting and recordkeeping requirements.

##### 40 CFR Parts 158 and 159

Environmental protection, Confidential business information, Pesticides and pest, Reporting and recordkeeping requirements.

40 CFR Part 160

Environmental protection, Laboratories, Pesticides and pest, Reporting and recordkeeping requirements.

40 CFR Part 162

Environmental protection, Administrative practice and procedure, Intergovernmental relations, Laboratories, Pesticides and pest.

40 CFR Part 164

Environmental protection, Administrative practice and procedure, Pesticides and pest.

40 CFR Part 166

Environmental protection, Administrative practice and procedure, Intergovernmental relations, Laboratories, Pesticides and pest.

40 CFR Part 168

Environmental protection, Administrative practice and procedure, Advertising, Pesticides and pest.

40 CFR Part 170

Environmental protection, Intergovernmental relations, Labeling, Occupational safety and health, Pesticides and pest.

40 CFR Part 171

Environmental protection, Indian lands, Intergovernmental relations, Laboratories, Pesticides and pest, Reporting and recordkeeping requirements.

40 CFR Part 172

Environmental protection, Intergovernmental relations, Labeling, Pesticides and pest, Reporting and recordkeeping requirements, Research.

40 CFR Part 180

Environmental protection, Administrative practice and procedure, Pesticides and pest, Reporting and recordkeeping requirements.

Dated: December 2, 2008.

**James B. Gulliford,**

*Assistant Administrator for 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. By revising § 152.1 to read as follows:

**§ 152.1 Scope.**

(a) Part 152 sets forth procedures, requirements and criteria concerning the registration of pesticide products under FIFRA section 3, including plant-incorporated protectants (PIPs). Unless specifically superseded by part 174, the regulations in part 152 apply to PIPs.

(b) Part 152 also describes associated regulatory activities affecting registration, as described in this paragraph.

(1) *Data compensation and exclusive use of data in support of registration.* Refer to subpart E of this part.

(2) *Rights and obligations of registrants.* Refer to subpart G of this part.

(3) *Classification of pesticide uses.* Refer to subpart I of this part.

(4) *Fees.* Refer to subpart U of this part.

(5) *Requirements pertaining to pesticide devices.* Refer to subpart Z of this part.

■ 3. In § 152.3 by removing the definitions of “Genetic material necessary for the production,” “In a living plant,” “Noncoding, nonexpressed nucleotide sequences,” “Pesticidal substance,” “Produce thereof,” and “Regulatory region”, and by revising the definitions of “Applicant,” and subparagraph (1) under the definition for “New use” to read as follows:

**§ 152.3 Definitions.**

\* \* \* \* \*

*Applicant* means a person who applies for a registration or amended registration under FIFRA sec. 3.

\* \* \* \* \*

*New use* \* \* \*

(1) Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of a tolerance or food additive regulation under section 408 of the Federal Food, Drug and Cosmetic Act;

\* \* \* \* \*

■ 4. In § 152.6 by revising paragraph (a)(2) to read as follows:

**§ 152.6 Substances excluded from regulation by FIFRA.**

\* \* \* \* \*

(a) \* \* \*

(2) *Claims.* The product must bear a sterilant claim, or a sterilant plus subordinate level disinfection claim. Products that bear antimicrobial claims solely at a level less than “sterilant” are not excluded and are jointly regulated by EPA and FDA.

\* \* \* \* \*

■ 5. By revising the section heading of § 152.10 to read as follows:

**§ 152.10 Products that are not pesticides because they are not intended for a pesticidal purpose.**

\* \* \* \* \*

■ 6. By revising the section heading of § 152.20 to read as follows:

**§ 152.20 Exemptions for pesticides adequately regulated by another Federal agency.**

\* \* \* \* \*

■ 7. Section 152.50 is amended by revising paragraph (i), and by adding paragraph (j) to read as follows:

**§ 152.50 Contents of application.**

\* \* \* \* \*

(i) *Statement concerning tolerances.*

(1) If the proposed labeling bears instructions for use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide chemical residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or degradation product), the applicant must submit a statement indicating whether such residues are authorized by a tolerance or exemption from the requirement of a tolerance issued under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA).

(2) If such residues have not been authorized, the application must be accompanied by a petition for establishment of appropriate tolerances or exemptions from the requirement of a tolerance, in accordance with part 180 of this chapter.

(j) *Fees.* (1) The applicant shall identify the appropriate fee category in the schedule provided for by FIFRA sec. 33, and shall submit the fee for that category as prescribed by the latest EPA notice of section 33 fees.

(2) If FIFRA sec. 33 is not in effect, the applicant shall submit any fees required by subpart U of this part, if applicable.

■ 8. By revising § 152.80 to read as follows:

**§ 152.80 General.**

This subpart E describes the information that an applicant must submit with his application for registration or amended registration to comply (and for the Agency to determine compliance) with the provisions of FIFRA sec. 3(c)(1)(F). This subpart also describes the procedures by which data submitters may challenge registration actions which allegedly failed to comply with these procedures. If the Agency determines that an applicant has failed to comply with the requirements and procedures in this subpart, the application may be denied. If the Agency determines, after

registration has been issued, that an applicant failed to comply with these procedures and requirements, the Agency may issue a notice of intent to cancel the product's registration.

#### § 152.83 [Amended]

■ 9. Section 152.83 is amended by removing the alpha paragraph designations from the definitions, and revising the reference to "FIFRA section 3(c)(1)(D)" to read "FIFRA section 3(c)(1)(F)", wherever it appears.

#### § 152.86 [Amended]

■ 10. Section 152.86 is amended by revising the reference "FIFRA section 3(c)(1)(D)" to read "FIFRA section 3(c)(1)(F)" wherever it appears.

■ 11. Section 152.93 is amended by revising the introductory text of paragraph (b)(2), paragraphs (b)(2)(iii) and (b)(3) to read as follows:

#### § 152.93 Citation of a previously submitted valid study.

\* \* \* \* \*

(b) \* \* \*

(2) *Citation with offer to pay compensation to the original data submitter.* The applicant may cite any valid study that is not subject to the exclusive use provisions of FIFRA section 3(c)(1)(F)(i) without written authorization from the original data submitter if the applicant certifies to the Agency that he has furnished to the original data submitter:

\* \* \* \* \*

(iii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F);

\* \* \* \* \*

(3) *Citation without authorization or offer to pay.* The applicant may cite any valid study without written authorization from, or offer to pay to, the original data submitter if the study was originally submitted to the Agency on or before the date that is 15 years before the date of the application for which it is cited, and the study is not an exclusive use study, as defined in § 152.83(c).

#### §§ 152.94, 152.95, 152.98, and 152.99 [Amended]

■ 12. Sections 152.94, 152.95, 152.98, are amended by revising the reference "FIFRA section 3(c)(1)(D)" to read "FIFRA section 3(c)(1)(F)" and § 152.99 is amended by revising the reference "FIFRA section 3(c)(1)(D)(ii)" to read "FIFRA section 3(c)(1)(F)(ii)" whichever occurs and wherever it occurs.

■ 13. By revising § 152.110 to read as follows:

#### § 152.110 Time for agency review.

The Agency will complete its review of applications as expeditiously as possible. Applications subject to specific timeframes under the fee schedule established by FIFRA section 33 will be reviewed within the timeframes established for the application or action type.

■ 14. In § 152.112 by revising paragraph (d) to read as follows, and in paragraph (g), by revising the phrase "under FFDCA sec. 408, sec. 409 or both; and" to read "under FFDCA sec. 408, and".

#### § 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 for the product by part 158 or part 161 of this chapter, as applicable.

\* \* \* \* \*

#### § 152.116 and § 152.135 [Amended]

■ 15. Section 152.116 and 152.135 are amended by revising the reference "FIFRA sec. 3(c)(1)(D)(i)" to read "FIFRA sec. 3(c)(1)(F)(i)" or by revising the reference "FIFRA sec. 3(c)(1)(D)" to read "FIFRA section 3(c)(1)(F)", whichever occurs and wherever it occurs.

■ 16. Section 152.125 is revised to read as follows:

#### § 152.125 Submission of information pertaining to adverse effects.

If at any time the registrant receives or becomes aware of any factual information regarding unreasonable adverse effects of the pesticide on the environment that has not previously been submitted to the Agency, the registrant shall, in accordance with FIFRA section 6(a)(2) and the requirements of part 159, subpart D of this chapter, provide such information to the Agency, clearly identified as FIFRA 6(a)(2) data.

#### PART 154—[AMENDED]

■ 17. The authority citation for part 154 is revised to read as follows:

Authority: 7 U.S.C. 136a, d, and w.

■ 18. Section 154.3 is revised to read as follows:

#### § 154.3 Definitions.

Terms used in this part have the same meaning as in the Act. In addition, as used in this part, the following terms shall apply:

*Act or FIFRA* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

*Administrator* means the Administrator of the Environmental Protection Agency or any officer or employee thereof to whom authority has been delegated to act for the Administrator.

*Confidential business information* means trade secrets or confidential commercial or financial information under FIFRA section 10(b) or 5 U.S.C. 552(b)(3) or (4).

*Other significant evidence* means factually significant information that relates to the uses of the pesticide and its adverse risk to man or to the environment but does not include evidence based only on misuse of the pesticide unless such misuse is widespread and commonly recognized practice.

*Person* means an applicant, registrant, manufacturer, pesticide user, environmental group, labor union, or other individual or group of individuals interested in pesticide regulation.

*Pesticide use* means a use of a pesticide (described in terms of the application site and other applicable identifying factors) that is included in the labeling of a pesticide product which is registered, or for which an application for registration is pending, and the terms and conditions (or proposed terms and conditions) of registration for the use.

*Terms and conditions of registration* means the terms and conditions governing lawful sale, distribution, and use approved in conjunction with registration, including labeling, use classification, composition, and packaging.

*Validated test* means a test determined by the Agency to have been conducted and evaluated in a manner consistent with accepted scientific procedures.

#### PART 155—[AMENDED]

■ 19. The authority citation for part 155 is revised to read as follows:

Authority: 7 U.S.C. 136a and 136w.

■ 20. By revising § 155.40(a) to read as follows:

#### § 155.40 General.

(a) *Purpose.* These regulations establish procedures for the registration review program required in FIFRA section 3(g). Registration review is the periodic review of a pesticide's registration to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration. Under

FIFRA section 3(g), each pesticide is required to be reviewed every 15 years.

\* \* \* \* \*

■ 21. By revising § 155.52(a) and (c), to read as follows:

**155.52 Stakeholder engagement.**

\* \* \* \* \*

(a) *Minutes of meetings with persons outside of government.* Subject to paragraph (c) of this section, if the Agency meets with one or more individuals that are not government employees to discuss matters relating to a registration review, the Agency will place in the docket a list of meeting attendees, minutes of the meeting, and any documents exchanged at the meeting, not later than the earlier of: (1) 45 days after the meeting; or (2) The date of issuance of the registration review decision.

\* \* \* \* \*

(c) *Confidential business information.* The Agency will identify, but not include in the docket, any confidential business information whose disclosure is prohibited by FIFRA section 10.

**PART 156—[AMENDED]**

■ 22. The authority citation for part 156 continues to read as follows:

Authority: 7 U.S.C. 136 - 136y.

■ 23. Section 156.10 is amended by revising paragraphs (i)(2)(ix), and (i)(2)(x)(D), and the introductory text of paragraph (j) to read as follows:

**§ 156.10 Labeling requirements.**

\* \* \* \* \*

(i) \* \* \*

(2) \* \* \*

(ix) Specific directions concerning the storage, residue removal and disposal of the pesticide and its container, in accordance with subpart H of this part. These instructions must be grouped and appear under the heading, "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See table in § 156.60(b))

(x) \* \* \*

(D) For total release foggers as defined in § 156.78(d)(1), the following statements must be included in the "Directions for Use."

\* \* \* \* \*

(j) *Statement of use classification.* Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing

directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of paragraph (j)(2) of this section.

\* \* \* \* \*

■ 24. Section 156.200 is amended by revising paragraph (c) to read as follows:

**§ 156.200 Scope and applicability.**

\* \* \* \* \*

(c) *Effective dates.* No product to which this subpart applies shall be distributed or sold without amended labeling by any registrant after April 21, 1994, or by any person after October 23, 1995.

■ 25. Section 156.203 is amended by revising the definition of "Restricted-entry interval" to read as follows:

**§ 156.203 Definitions.**

\* \* \* \* \*

*Restricted-entry interval or REI* means the time after the end of a pesticide application during which entry to the treated area is restricted.

■ 26. Section 156.204 is amended by revising paragraph (b) to read as follows:

**§ 156.204 Modification and waiver of requirements.**

\* \* \* \* \*

(b) *Other modifications.* The Agency, pursuant to this subpart and authorities granted in FIFRA sections 3, 6, and 12, may, on its initiative or based on data submitted by any person, modify or waive the requirements of this subpart, or permit or require alternative labeling statements. Supporting data may be either data conducted according to Subdivisions U or K of the Pesticide Assessments guidelines or data from medical, epidemiological, or health effects studies. A registrant who wishes to modify any of the statements required in §§ 156.206, 156.208, 156.210, or 156.212 must submit an application for amended registration unless specifically directed otherwise by the Agency.

**§§ 156.206, 156.208, 156.210, and 156.212 [Amended]**

■ 27. Sections 156.206(e), 156.208(c)(1), 156.210(b)(1), and 156.212(d)(2) are amended by revising the reference "§ 156.10(h)(1)" to read "§ 156.62", wherever it occurs.

**PART 157—[AMENDED]**

■ 28. The authority citation for part 157 continues to read as follows:

Authority: 7 U.S.C. 136w.

**§ 157.21 [Amended]**

■ 29. Section 157.21 is amended by removing the alpha paragraph designations from the definitions.

**PART 158—[AMENDED]**

■ 30. The authority citation for part 158 continues to read as follows:

Authority: 7 U.S.C. 136-136y; 21 U.S.C. 346a.

**§ 158.220 [Amended]**

■ 31. In § 158.220, the title of the table in paragraph (c) is revised to read "Table—Experimental Use Permit Data Requirements for Product Performance".

**§ 158.230 [Amended]**

■ 32. In § 158.230, the title of the table in paragraph (c) is revised to read "Table—Experimental Use Permit Toxicity Data Requirements."

**§ 158.243 [Amended]**

■ 33. In § 158.243, the title of the table in paragraph (c) is revised to read "Table—Experimental Use Permit Terrestrial and Aquatic Nontarget Organism Data Requirements."

**§ 158.260 [Amended]**

■ 34. In § 158.260, the title of the table in paragraph (c) is revised to read "Table—Experimental Use Permit Environmental Fate Data Requirements."

**PART 159—[AMENDED]**

■ 35. The authority citation for part 159 continues to read as follows:

Authority: 7 U.S.C. 136 - 136y.

■ 36. Section 159.153 is amended by revising the introductory text of paragraph (b) to read as follows:

**§ 159.153 Definitions.**

\* \* \* \* \*

(b) For purposes of reporting information pursuant to FIFRA section 6(a)(2), the following definitions apply only to this subpart:

\* \* \* \* \*

■ 37. Section 159.160 is amended by revising paragraph (b)(4) to read as follows:

**§ 159.160 Obligations of former registrants.**

\* \* \* \* \*

(b) \* \* \* (4) The information pertains solely to a formerly registered product that no longer meets the definition of "pesticide" in section 2(u) of FIFRA.

\* \* \* \* \*

**§ 159.165 [Amended]**

■ 38. Section 159.165 is amended in paragraph (a)(2) by revising the reference “40 CFR 156.10(h)” to read “40 CFR 156.62” and in the introductory text of paragraph (d)(2) by revising the phrase “90 calendar days or less,” to read “more than 90 calendar days.”

**PART 160—[AMENDED]**

■ 39. The authority citation for part 160 is revised to read as follows:

**Authority:** 7 U.S.C. 136a, 136c, 136d, 136f, 136j, 136t, 136v, 136w; 21 U.S.C. 346a, 371, Reorganization Plan No. 3 of 1970.

■ 40. Section 160.1 is revised to read as follows:

**§ 160.1 Scope and applicability.**

(a) This part prescribes good laboratory practices for conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA. This part is intended to assure the quality and integrity of data submitted pursuant to sections 3, 4, 5, 8, 18 and 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and section 408 or 409 of the Federal Food, Drug and Cosmetic Act.

(b) This part applies to any study described by paragraph (a) of this section which any person conducts, initiates, or supports on or after October 16, 1989.

■ 41. In § 160.3 revise the introductory text of the definition for *Application for research or marketing permit*, and in the same definition, revise paragraph (5), and revise the definition for “person” to read as follows:

**§ 160.3 Definitions.**

\* \* \* \* \*

*Application for research or marketing permit* means any of the following:

\* \* \* \* \*

(5) A petition or other request for establishment or modification of a food additive regulation or other clearance by EPA under FFDC section 409 that was submitted prior to August 3, 1996.

\* \* \* \* \*

*Person* means an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit thereof, or any other legal entity.

\* \* \* \* \*

**PART 162—[AMENDED]**

■ 42. The authority citation for part 162 continues to read as follows:

**Authority:** 7 U.S.C. 136v, 136w.

■ 43. Section 162.151 is revised to read as follows:

**§ 162.151 Definitions.**

Terms used in this part have the same meaning as in the Act and part 152 of this chapter. In addition, as used in this subpart, the following terms shall apply:

*Federally registered* means currently registered under section 3 of the Act, after having been initially registered under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 by the Secretary of Agriculture or under FIFRA by the Administrator.

*Manufacturing-use product* means any pesticide product other than a product to be labeled with directions for end use. This term includes any product intended for use as a pesticide after reformulation or repackaging.

*New product* means a pesticide product which is not a federally registered product.

*Pest problem* means:

- (1) A pest infestation and its consequences, or
- (2) Any condition for which the use of plant regulators, defoliants, or desiccants would be appropriate.

*Product or pesticide product* means a pesticide offered for distribution and use, and includes any labeled container and any supplemental labeling.

*Similar composition* means a pesticide product which contains only the same active ingredient(s), or combinations of active ingredients, and which is in the same toxicity category, as defined in § 156.62 of this chapter, as a federally registered pesticide product.

*Similar product* means a pesticide product which, when compared to a federally registered product, has a similar composition and a similar use pattern.

*Similar use pattern* means a use of a pesticide product which, when compared to a federally registered use of a product with a similar composition, does not require a change in precautionary labeling under part 156 of this chapter, and which is substantially the same as the federally registered use. Registrations involving changed use patterns are not included in this term.

*Special local need* means an existing or imminent pest problem within a State for which the State lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available.

*State or State lead agency* means the State agency designated by the State to be responsible for registering pesticides

to meet special local needs under section 24(c) of the Act.

■ 44. Section 162.152 is amended by revising paragraph (b)(1)(i) to read as follows:

**§ 162.152 State registration authority.**

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(i) Subject to the provisions of paragraphs (a) and (b)(1)(ii) through (iv) of this section, States may register any new use of a federally registered pesticide product.

\* \* \* \* \*

■ 45. Section 162.153 is amended by redesignating paragraph (a)(6) as paragraph (j), and by revising the last sentence of paragraph (c)(2) to read as follows:

**§ 162.153 State registration procedures.**

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

Such determinations may also involve consideration of the effect of the anticipated classification of the product or use under paragraph (g) of this section.

\* \* \* \* \*

**PART 164—[AMENDED]**

■ 46. The authority citation for part 164 continues to read as follows:

**Authority:** 7 U.S.C. 136d.

■ 47. Section 164.2 is amended by revising paragraphs (l)(2) and (s) to read as follows:

**§ 164.2 Definitions.**

\* \* \* \* \*

(l) \* \* \*

(2) *Qualification.* A judicial officer shall be a permanent or temporary employee or officer of the Agency who may perform other duties for the Agency. Such judicial officer shall not be employed by the Office of Prevention, Pesticides, and Toxic Substances or have any connection with the preparation or presentation of evidence for a hearing.

\* \* \* \* \*

(s) The term *Respondent* means the Assistant Administrator of the Office of Prevention, Pesticides, and Toxic Substances.

\* \* \* \* \*

**PART 166—[AMENDED]**

■ 48. The authority citation for part 166 is revised to read as follows:

**Authority:** 7 U.S.C. 136p, and 136w.

■ 49. Section 166.3 is revised to read as follows:

**§ 166.3 Definitions.**

Terms used in this part have the same meaning as in the Act. In addition, as used in this part, the following terms shall apply:

*Act* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

*Agency and EPA* mean the U. S. Environmental Protection Agency.

*Beneficial organism* means any pollinating insect, or any pest predator, parasite, pathogen or other biological control agent which functions naturally or as part of an integrated pest management program to control another pest.

*Emergency condition* means an urgent, non-routine situation that requires the use of a pesticide(s) and shall be deemed to exist when:

(1) No effective pesticides are available under the Act that have labeled uses registered for control of the pest under the conditions of the emergency; and

(2) No economically or environmentally feasible alternative practices which provide adequate control are available; and

(3) The situation:

(i) Involves the introduction or dissemination of an invasive species or a pesticide new to or not theretofore known to be widely prevalent or distributed within or throughout the United States and its territories; or

(ii) Will present significant risks to human health; or

(iii) Will present significant risks to threatened or endangered species, beneficial organisms, or the environment; or

(iv) Will cause significant economic loss due to:

(A) An outbreak or an expected outbreak of a pest; or

(B) A change in plant growth or development caused by unusual environmental conditions where such change can be rectified by the use of a pesticide(s).

*First food use* means the use of a pesticide on a food or in a manner which otherwise would be expected to result in residues in a food, if no tolerance or exemption from the requirements of a tolerance for residues of the pesticide on any food has been established for the pesticide under section 408 of the Federal Food, Drug, and Cosmetic Act.

*Food* means any article used for food or drink for man or animals.

*Invasive species* means, with respect to a particular ecosystem, any species that is not native to that ecosystem, and whose introduction does or is likely to

cause economic or environmental harm or harm to human health.

*IR-4* means the Interregional Research Project No. 4, a cooperative effort of the state land grant universities, the U.S. Department of Agriculture and EPA, to address the chronic shortage of pest control options for minor crops, which are generally of too small an acreage to provide economic incentive for registration by the crop protection industry.

*New chemical* means an active ingredient not contained in any currently registered pesticide.

*Significant economic loss* means that, compared to the situation without the pest emergency and despite the best efforts of the affected persons, the emergency conditions at the specific use site identified in the application are reasonably expected to cause losses meeting any of the following criteria:

(1) For pest activity that primarily affects the current crop or other output, one or more of the following:

(i) Yield loss greater than or equal to 20%.

(ii) Economic loss, including revenue losses and cost increases, greater than or equal to 20% of gross revenues.

(iii) Economic loss, including revenue losses and cost increases greater than or equal to 50% of net revenues.

(2) For any pest activity where EPA determines that the criteria in paragraph (1) of this definition would not adequately describe the expected loss, substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity.

*Special Review* means any interim administrative review of the risks and benefits of the use of a pesticide conducted pursuant to the provisions of part 154 of this chapter, or § 162.11 of this chapter prior to November 27, 1985, or any subsequent version of those rules.

*Unreasonable adverse effects on the environment* means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.

**PART 168—[AMENDED]**

■ 50. The authority citation for part 168 continues to read as follows:

**Authority:** 7 U.S.C. 136 - 136y.

■ 51. Section 168.65 is amended by revising the last sentence of paragraph (b)(1)(ii), and paragraph (b)(1)(vii), to read as set forth below.

**§ 168.65 Pesticide export label and labeling requirements.**

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(ii) \* \* \* Where the U.S. warning or caution statement, as translated, is obviously inappropriate to protect residents of the importing country (for example, where a statement calls for a gas mask meeting the specifications of the National Institute of Occupational Safety and Health), an equivalent caution must be substituted.

\* \* \* \* \*

(vii) *Additional warning for highly toxic pesticides.* If the pesticide, device or active ingredient is highly toxic to humans, the skull and crossbones, the word "Poison," and a first aid statement must appear on the label. The word "Poison" and the first aid statement shall be in English and in the appropriate foreign languages, as described in paragraph (b)(4) of this section. The skull and crossbones may be in red or black. For criteria on what pesticides are highly toxic, see § 156.62 of this chapter.

\* \* \* \* \*

**PART 170—[AMENDED]**

■ 52. The authority citation for part 170 continues to read as follows:

**Authority:** 7 U.S.C. 136w.

**§ 170.5 [Removed]**

■ 53. Section 170.5 is removed.

**§ 170.104 [Amended]**

■ 54. Section 170.104 is amended by revising the acronym "PPE" in paragraph (b)(2)(iii) to read "personal protective equipment" and by removing paragraph (c).

**§ 170.112 [Amended]**

■ 55. Section 170.112 is amended by removing paragraphs (e)(7)(i) and (e)(7)(iv), and by redesignating paragraphs (e)(7)(ii) and (e)(7)(iii) as paragraphs (e)(7)(i) and (e)(7)(ii), respectively.

■ 56. Section 170.130 is amended by revising paragraph (a)(3)(i) to read as follows, by removing paragraph (a)(3)(iii) and by revising paragraph (d)(3) to read as follows:.

**§ 170.130 Pesticide safety training for workers.**

(a) \* \* \*

(3) \* \* \* (i) *Information before entry.*

Except as provided in paragraph (a)(2) of this section, before a worker enters any areas on the agricultural establishment where, within the last 30

days a pesticide to which this subpart applies has been applied or the restricted-entry interval for such pesticide has been in effect, the agricultural employer shall assure that the worker has been provided the pesticide safety information specified in paragraph (c) of this section, in a manner that agricultural workers can understand, such as by providing written materials or oral communication or by other means. The agricultural employer must be able to verify compliance with this requirement.

\* \* \* \* \*

(d) \* \* \*

(3) Any person who issues an EPA-approved Worker Protection Standard worker training certificate must assure that the worker who receives the training certificate has been trained in accordance with paragraph (d)(4) of this section.

\* \* \* \* \*

**§ 170.204 [Amended]**

■ 57. Section 170.204 is amended by removing paragraph (c).

**PART 171—[AMENDED]**

■ 58. The authority citation for part 171 is revised to read as follows:

**Authority:** 7 U.S.C. 136i and 136w.

■ 59. Section 171.2 is amended by revising the introductory text of paragraph (a) and by revising paragraph (b)(4) to read as follows:

**§ 171.2 Definitions.**

(a) Terms used in this subpart have the same meaning as in the Act. In addition, the following definitions are applicable to all aspects of the certification of pesticide applicator program in this part:

\* \* \* \* \*

(b) \* \* \*

(4) The term *uncertified person* means any person who is not holding a currently valid certification document indicating that he is certified under section 11 of FIFRA in the category of the restricted use pesticide made available for use.

\* \* \* \* \*

**PART 172—[AMENDED]**

■ 60. 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.

■ 61. Section 172.1 is revised to read as follows

**§ 172.1 Definitions.**

Terms used in this part have the same meaning as in the Act. In addition, as used in this part, the following terms shall apply:

*Act* means the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

*Applicant* means any person who applies for an experimental use permit pursuant to section 5 of the Act.

*Cooperator* means any person who grants permission to a permittee or a permittee's designated participant for the use of an experimental use pesticide at an application site owned or controlled by the cooperator.

*Experimental animals* means individual animals or groups of animals, regardless of species, intended for use and used solely for research purposes. The term does not include animals intended to be used for any food purposes

*Participant* means any person acting as a representative of the permittee and responsible for making available for use, or supervising the use or evaluation of, an experimental use pesticide to be applied at a specific application site.

*Permittee* means any applicant to whom an experimental use permit has been granted.

*Value for pesticide purposes* means that characteristic of a substance or mixture of substances which produces an efficacious action on a pest.

**§ 172.3 [Amended]**

■ 62. Section 172.3(d) is amended by removing the third sentence which reads "Subdivision I of the Pesticide Assessment Guidelines provides guidance on the procedures, data requirements, and general aspects pertaining to the issuance and use of EUPs."

■ 63. Section 172.4 is amended by revising paragraph (b)(2)(i) and (ii) to read as follows:

**§ 172.4 Applications.**

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(i) Submit evidence that a tolerance or exemption from the requirement of a tolerance has been established for residues of the pesticide in or on such food or feed under section 408 of the Federal Food, Drug, and Cosmetic Act; or

(ii) Submit a petition proposing establishment of a tolerance or an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act; or

\* \* \* \* \*

■ 64. Section 172.21 is revised to read as follows:

**§ 172.21 Definitions.**

Terms used in this subpart shall have the meaning set forth in FIFRA and in § 172.1.

*Designated State Agency* means the State agency designated by State law or other authority to be responsible for registering pesticides to meet special local needs.

*Public or Private Agricultural Research Agency or Educational Institution* means any organization engaged in research pertaining to the agricultural use of pesticides, or any educational institution engaged in pesticide research. Any research agency or educational institution whose principal function is to promote, or whose principal source of income is directly derived from, the sale or distribution of pesticides (or their active ingredients) does not come within the meaning of this term.

■ 65. Section 172.24 is amended by revising paragraphs (b)(3),(d)(1)(i) and (d)(1)(ii) to read as follows:

**§ 172.24 State issuance of permits.**

\* \* \* \* \*

(b) \* \* \*

(3) For use of a restricted use pesticide only if the pesticide is to be used by, or under the direct supervision of, an applicator certified in accordance with section 11 of FIFRA.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(i) A tolerance or exemption from the requirement of a tolerance has been established for residues of the pesticide in or on such food or feed under section 408 of the Federal Food, Drug and Cosmetic Act; and

(ii) The proposed program would not reasonably be expected to result in residues of the pesticide in or on such food or feed in excess of that authorized under section 408 of the Federal Food, Drug and Cosmetic Act; and

\* \* \* \* \*

■ 66. Section 172.26 is amended by revising paragraph (c)(1)(iii) to read as follows:

**§ 172.26 EPA review of permits.**

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

(iii) That new evidence demonstrates that any tolerance upon which the permit is based will be inadequate to protect the public health, or that any exemption from the requirement for a tolerance is no longer appropriate; or

\* \* \* \* \*



§ 172.46 [Amended]

■ 67. In the introductory text to § 172.46(c), revise "161.31" to read "161.32."

PART 180—[AMENDED]

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

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

■ 69. Part 180 is amended as follows:

■ a. By revising the part heading to read "Tolerances and Exemptions for Pesticide Chemical Residues in Food."

■ b. By removing the center heading that immediately follows the Subpart A heading.

■ c. Removing the center heading that immediately follows the Subpart B heading.

■ d. By removing the two center headings that immediately precede § 180.29.

■ 70. Section 180.7 is amended by revising the last sentence in paragraph (b)(1), the last sentence in paragraph (d) and by revising the next to the last sentence in paragraph (f) to read as follows:

§ 180.7 Petitions proposing tolerances or exemptions for pesticide residues in or on raw agricultural commodities or processed foods.

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \* The electronic copy should be formatted according to the Office of Pesticide Programs' current standard for electronic data submission as specified at http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm.

\* \* \* \* \*

(d) \* \* \* The Administrator shall make the full text of the summary referenced in paragraph (b)(1) of this section available to the public in the public docket at http://www.regulations.gov no later than publication in the Federal Register of the notice of the petition filing.

\* \* \* \* \*

(f) \* \* \* The notice shall explicitly reference the specific docket identification number in the public docket at http://www.regulations.gov where the full text of the summary required in paragraph (b) of this section is located, and refer interested parties to this document for further information on the petition. \* \* \*

\* \* \* \* \*

■ 71. Section 180.34 is amended by revising the introductory text of paragraph (e) to read as follows:

§ 180.34 Tests on the amount of residue remaining.

\* \* \* \* \*

(e) Each of the following groups of crops lists raw agricultural commodities that are considered to be related for the purpose of paragraph (d) of this section. Commodities not listed in this paragraph are not considered to be related for the purpose of paragraph (d) of this section.

\* \* \* \* \*

[FR Doc. E8-29375 Filed 12-11-08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R10-OAR-2008-0166; FRL-8750-2]

Approval and Promulgation of Implementation Plans; Alaska; Interstate Transport of Pollution

AGENCY: Environmental Protection Agency (EPA).

ACTION: Correcting amendment.

SUMMARY: EPA issued a direct final rule on October 15, 2008, entitled "Approval and Promulgation of Implementation Plans; Alaska; Interstate Transport of Pollution." This document makes a minor correction to the October 15, 2008, action to correct a typographical error in the regulatory text for the rule.

DATES: Effective Date: This document is effective on December 15, 2008.

FOR FURTHER INFORMATION CONTACT: For questions regarding this correction, contact Donna Deneen, Office of Air, Waste, and Toxics, Mail Code (AWT-107), Environmental Protection Agency Region 10, Seattle, WA 98121; telephone number: (206) 553-6706; fax number: (206) 553-0110; e-mail address: deneen.donna@epa.gov.

SUPPLEMENTARY INFORMATION:

Background

The EPA issued "Approval and Promulgation of Implementation Plans; Alaska; Interstate Transport of Pollution" as a direct final rule on October 15, 2008, 73 FR 60955. This direct final rule approved the State of Alaska's demonstration that its emissions do not significantly contribute to nonattainment or interfere with maintenance of the NAAQS in another state, or interfere with measures required to be included in the SIP for any other State to prevent significant deterioration of air quality or to protect visibility. For more information about this action, please see the proposed and

final rulemaking actions which are available at www.regulations.gov and also in the Federal Register at 73 FR 60955 and 73 FR 60996.

Need for Correction

As published, the regulatory text in the direct final regulation contains a minor error that, if not corrected, prevents publication of the regulatory amendment in the Code of Federal Regulations. EPA finds that there is good cause to make this correction without providing for notice and comment because neither notice nor comment is necessary and would not be in the public interest due to the nature of the correction which is minor, technical and does not change the obligations already existing in the rule. EPA finds that the corrections are merely correcting the numbering in the amendatory language so that the provision may be published in the Code of Federal Regulations.

Corrections of Publication

In the regulatory text to the direct final rule for "Approval and Promulgation of Implementation Plans; Alaska; Interstate Transport of Pollution," October 15, 2008, 73 FR 60955, EPA is correcting an inadvertent minor error in instruction number 2. Instruction number 2 reads "Section 52.97 is added to read as follows:", but in the actual text just below that statement the added section is designated inadvertently as "Section 52.70." EPA is correcting this inadvertent minor error so that the amendatory instruction number 2 continues to read "Section 52.97 is added to read as follows:", but the actual text just below that statement "§ 52.70" is changed to read "§ 52.97."

§ 52.97 [Corrected]

In FR Doc. E8-24279 published October 15, 2008 (73 FR 60955), make the following correction. On page 60957, in the center column, the section heading following amendatory instruction 2 is corrected to read as follows:

§ 52.97 Interstate Transport for the 1997 8-hour ozone and PM2.5 NAAQS.

\* \* \* \* \*

Dated: December 3, 2008.

Elin D. Miller,

Regional Administrator, Region 10.

[FR Doc. E8-29231 Filed 12-11-08; 8:45 am]

BILLING CODE 6560-50-P