

proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. 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, Incorporation by reference, Intergovernmental relations, Ozone.

Dated: April 9, 2009.

**Bharat Mathur**,

*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 YY—Wisconsin

■ 2. Section 52.2585 is amended by adding paragraph (v) to read as follows:

##### § 52.2585 Control Strategy: Ozone.

\* \* \* \* \*

(v) On July 28, 2008, the Wisconsin Department of Natural Resources requested that EPA find that the Milwaukee-Racine, WI nonattainment area, attained the revoked 1-hour ozone National Ambient Air Quality Standard (NAAQS). After review of this submission, EPA approves this request.

[FR Doc. E9-9364 Filed 4-23-09; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2008-0526; FRL-8411-9]

#### Penoxsulam; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of penoxsulam in or on almond hulls; grape; nut, tree, group 14; and pistachio. Dow AgroSciences, LLC., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 24, 2009. Objections and requests for hearings must be received on or before

June 23, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0526. All documents in the docket are listed in the docket index available at <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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open 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:

Philip V. Errico, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6663; e-mail address: [errico.philip@epa.gov](mailto:errico.philip@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 an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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**.

###### B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

###### C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2008-0526 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before June 23, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2008-0526, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through

Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## II. Petition for Tolerance

In the **Federal Register** of August 13, 2008 (73 FR 47186) (FRL-8375-8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F7369) by Dow AgroSciences, LLC., 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR 180.605 be amended by establishing tolerances for residues of the herbicide penoxsulam, 2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide in or on nut, tree, group 14; grape; almond, hulls, and pistachio all at 0.1 parts per million (ppm). That notice referenced a summary of the petition prepared by Dow AgroSciences LLC, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue..."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of penoxsulam

on almond hulls; grape; nut, tree, group 14, and pistachio all at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Penoxsulam exhibited minimal acute toxicity in the available studies. In subchronic and chronic feeding studies in rats and dogs, the most sensitive target organ was the urothelium of the urinary system. In subchronic and chronic feeding studies in mice, no effects of toxicological significance were observed. No developmental toxicity was observed in the developmental toxicity studies in rats and rabbits and there was no increased quantitative or qualitative susceptibility of fetuses, as compared to dams. In a two-generation reproduction study in rats, delays in preputial separation were noted; however, no other endpoints of reproductive toxicity or offspring growth and survival were affected by treatment. There was no increased quantitative or qualitative susceptibility of fetuses or offspring, as compared to adults. No treatment-related neurotoxicity was observed in acute or chronic neurotoxicity studies in rats, or in any of the other available studies on penoxsulam. No systemic or dermal toxicity was noted in a 28-day dermal toxicity study in rats.

With respect to carcinogenicity, penoxsulam was classified as having suggestive evidence of carcinogenicity. The classification was based on an increase in large granular lymphocyte leukemia (also called mononuclear cell leukemia (MNCL)). EPA concluded that the cancer risk to humans is negligible. The MNCL seen in the Fisher 344 rat study appears not to be treatment related because it was only seen in male rats, there was a lack of dose-response across the treatment groups (i.e., incidence did not increase with increasing dose), and Fisher 344 rats are known to be susceptible to MNCL, especially as they age. MNCL in Fisher 344 rats has not been found in other mammals, and there is no comparable tumor seen in humans. Finally, there is no other evidence on penoxsulam to indicate a cancer concern, including the fact that no cancer concerns were

identified in the mouse carcinogenicity study; there is no evidence that penoxsulam is genotoxic; and other chemicals in the class of compounds (triazolopyrimidines) have not shown evidence of MNCL in Fisher 344 rats. EPA determined that the chronic assessment is considered to be protective of potential cancer risks. Penoxsulam did not demonstrate any mutagenic potential in a battery of four mutagenicity studies. There is not a concern for mutagenicity resulting from exposure to penoxsulam.

Specific information on the studies received and the nature of the adverse effects caused by penoxsulam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document *Penoxsulam Risk Assessment* at Appendix A in docket ID number EPA-HQ-OPP-2008-0526 and in the final rule published in the **Federal Register** of September 24, 2004 (EPA-HQ-OPP-2004-0286), (FRL-7678-6).

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for penoxsulam used for human risk assessment can be found at <http://www.regulations.gov> in document Penoxsulam Risk Assessment at Appendix A in docket ID number EPA-HQ-OPP-2008-0526 and in the final rule published in the **Federal Register** of September 24, 2004 (EPA-HQ-OPP-2004-0286), (FRL-7678-6).

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to penoxsulam, EPA considered exposure under the petitioned-for tolerances as well as all existing penoxsulam tolerances in 40 CFR 180.605.

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for penoxsulam; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture 1994-1996 and 1998 Continuing Survey of Food Intake by Individuals. As to residue levels in food, EPA used tolerance level residues and 100% crop treated, and incorporated default processing factors for processed food forms.

iii. *Cancer.* Penoxsulam has been classified as having "suggestive evidence for carcinogenic potential" based on some evidence of mononuclear cell leukemia (MNCL) in a penoxsulam cancer study in Fisher 344 rats. However, the Agency concluded that the cancer risk to humans is negligible based on the following considerations. First, it is questionable that the MNCL seen in the Fisher 344 rat study was treatment related because it was only seen in male rats, there was a lack of dose-response across the treatment groups (i.e., incidence did not increase with increasing dose), and Fisher 344

rats are known to be susceptible to MNCL, especially as they age. Second, MNCL in Fisher 344 rats is of questionable significance for humans because it has not been found in other mammals, and there is no comparable tumor seen in humans. Finally, there is no other evidence on penoxsulam to indicate a cancer concern, including the fact that no cancer concerns were identified in the mouse carcinogenicity study; there is no evidence that penoxsulam is genotoxic; and other chemicals in the class of compounds (triazolopyrimidines) have not shown evidence of MNCL in Fisher 344 rats.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for penoxsulam. Tolerance level residues and/or 100% crop treated were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency considered screening level water exposure models in the dietary exposure analysis and risk assessment for penoxsulam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of penoxsulam. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the FIRST model for surface water and the Screening Concentration in Ground Water (SCI-GROW) model for ground water, the estimated drinking water concentrations (EDWCs) of penoxsulam for chronic exposures for non-cancer assessments are estimated to be 0.9 parts per billion (ppb) for surface water and 23.3 ppb for ground water.

In addition to uses that may result in the transport of penoxsulam residues to surface and/or ground water, penoxsulam may be applied directly to water, at a maximum rate of 150 ppb, for aquatic weed control. For chronic dietary risk assessment, the water concentration value of 150 ppb from the registered aquatic use was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Penoxsulam is currently registered for the following uses that could result in residential exposures following use on lawns and treatment of residential aquatic sites. EPA assessed residential exposure using the following

assumptions: exposures can be of short- and intermediate-term durations and can be through dermal or oral routes.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found penoxsulam to share a common mechanism of toxicity with any other substances, and penoxsulam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that penoxsulam does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

### D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No developmental toxicity was observed in the developmental toxicity studies in rats and rabbits and there was no increased quantitative or qualitative susceptibility of fetuses, as compared to dams. In a two-generation reproduction study in rats, delays in preputial separation were noted; however, no other endpoints of reproductive toxicity or offspring growth and survival were affected by treatment. There was no increased quantitative or qualitative susceptibility of fetuses or offspring, as compared to adults. There are no residual uncertainties for pre- and/or post-natal toxicity resulting from exposure to penoxsulam and there is no

evidence of quantitative or qualitative susceptibility in the toxicological data.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for penoxsulam is complete, except for immunotoxicity testing. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect well after the tolerance petition was submitted, these studies are not yet available for penoxsulam. In the absence of specific immunotoxicity studies, EPA has evaluated the available penoxsulam toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. There was no evidence of adverse effects on the organs of the immune system in any study with penoxsulam. Based on these considerations, EPA does not believe that conducting a special series 870.7800 immunotoxicity study will result in a point of departure less than the NOAEL of 14.7 milligrams/kilograms/day (mg/kg/day) used in calculating the cPAD for penoxsulam; therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity.

ii. There is no indication that penoxsulam is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that penoxsulam results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment utilizes proposed tolerance level residues and 100% crop treated for all commodities. EPA made conservative (protective) assumptions in the residue estimates used to assess exposure to penoxsulam in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by penoxsulam.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates

to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, penoxsulam is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to penoxsulam from food and water will utilize 7.1% of the cPAD for all infants, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Penoxsulam is currently registered for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to penoxsulam.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 1,500 to children from oral post application exposure from turf treated with penoxsulam and 5,500 from adults applying penoxsulam to residential turf. As the aggregate MOE is greater than 100, the short-term aggregate risks to children and adults do not exceed EPA's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Penoxsulam is currently registered for use(s) that could result in intermediate-term residential exposure. However, the Agency has determined that it is not appropriate to aggregate these

intermediate-term exposures with chronic exposure to penoxsulam through food and water. Therefore, intermediate-term aggregate risk estimates are equivalent to the chronic aggregate risk estimates discussed above.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to penoxsulam residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (high performance liquid chromatography with tandem mass spectroscopy-mass spectroscopy detector (LC/MS/MS), is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

There are no CODEX maximum residue limits (MRLs) for residues of penoxsulam in almond, hulls; grape; nut, tree, group 14, and pistachio.

#### **V. Conclusion**

Therefore, tolerances are established for residues of penoxsulam on almond hulls; grape; nut, tree, group 14, and pistachio all at 0.01 ppm.

#### **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under section 408(d) of FFDCFA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCFA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(m)(4) of FFDCFA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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).

**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 to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: April 17, 2009.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

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

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

■ 2. Section 180.605 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.605 Penoxsulam; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Almond, hulls .....	0.01
* * * * *	
Grape .....	0.01
Nut, tree, group 14 .....	0.01
Pistachio .....	0.01
* * * * *	

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[FR Doc. E9-9441 Filed 4-23-09; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 228**

**[EPA-R10-OW-2008-0826; FRL-8893-1]**

**Ocean Dumping; Designation of Ocean Dredged Material Disposal Sites Offshore of the Umpqua River, Oregon**

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

**ACTION:** Final rule.

**SUMMARY:** This action finalizes the designation of the Umpqua River ocean dredged material sites pursuant to the Marine Protection, Research and Sanctuaries Act, as amended (MPRSA). The new sites are needed primarily to serve the long-term need for a location to dispose of material dredged from the Umpqua River navigation channel, and to provide a location for the disposal of dredged material for persons who have received a permit for such disposal. The

newly designated sites will be subject to ongoing monitoring and management specified in this rule and in the Site Management and Monitoring Plan, which is also finalized as part of this action. The monitoring and management requirements will help to ensure ongoing protection of the marine environment.

**DATES:** *Effective Date:* This final rule will be effective May 26, 2009.

**ADDRESSES:** For more information on this final rule, Docket ID No. EPA-R10-OW-2008-0826 use one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for accessing the docket and materials related to this final rule.

- *E-mail:*

*Freedman.Jonathan@epa.gov*

- *Mail:* Jonathan Freedman, U.S.

Environmental Protection Agency, Region 10, Office of Ecosystems, Tribal and Public Affairs (ETPA-083), Aquatic Resources Unit, 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101.

Publicly available docket materials are available either electronically at *http://www.regulations.gov*, or in hard copy during normal business hours at the U.S. Environmental Protection Agency, Region 10, Library, 10th Floor, 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101. For access to the documents at the Region 10 Library, contact the Region 10 Library Reference Desk at (206) 553-1289, between the hours of 9 a.m. to 11:30 a.m., and between the hours of 1 p.m. to 4 p.m., Monday through Friday, excluding legal holidays, for an appointment.

**FOR FURTHER INFORMATION CONTACT:**

Jonathan Freedman, U.S. Environmental Protection Agency, Region 10, Office of Ecosystems, Tribal and Public Affairs (ETPA-083), Aquatic Resources Unit, 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101, phone number:

(206) 553-0266, e-mail:

*freedman.jonathan@epa.gov*, or contact

Jessica Winkler, U.S. Environmental Protection Agency, Region 10, Office of Ecosystems, Tribal and Public Affairs (ETPA-083), Aquatic Resources Unit, 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101, phone number:

(206) 553-7369, e-mail:

*winkler.jessica@epa.gov*.

**SUPPLEMENTARY INFORMATION:** On November 25, 2008, EPA published a proposed rule at 73 FR 71575 to designate two new ocean dredged material disposal sites near the mouth of the Umpqua River, Oregon and to withdraw an earlier proposed rule to designate a single site. EPA received one comment on the proposed rule.