

- 2. Section 180.920 is amended in the table by removing the entry Isophorone.
- Section 180.1270 is added to subpart D to read as follows:

**§ 180.1270 Isophorone; exemption from the requirement of a tolerance.**

Isophorone (CAS Reg. No. 78-59-1) is exempt from the requirement of a tolerance when used as an inert ingredient in pesticide formulations applied to beets, ginseng, rice, spinach, sugar beets, and Swiss chard.

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0253; FRL-8082-3]

**Inert Ingredient; Revocation of the Tolerance Exemption for Mono- and Bis-(1H, 1H, 2H, 2H-perfluoroalkyl) Phosphates Where the Alkyl Group is Even Numbered and in the C<sub>6</sub>-C<sub>12</sub> Range**

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

**ACTION:** Final rule.

**SUMMARY:** EPA is revoking, under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(e)(1), the existing exemption from the requirement of a tolerance for residues of the inert ingredient “Mono- and bis-(1H, 1H, 2H, 2H-perfluoroalkyl) phosphates where the alkyl group is even numbered and in the C<sub>6</sub>-C<sub>12</sub> range” under 40 CFR 180.920. The regulatory action contributes toward the Agency’s tolerance reassessment requirements under FFDCA section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required by August 2006 to reassess the tolerances that were in existence on August 2, 1996. This regulatory action counts as a tolerance reassessment toward the August 2006 review deadline.

**DATES:** This rule is effective February 9, 2008.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0253. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as

copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP 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:**

Karen Angulo, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 306-0404; e-mail address: [angulo.karen@epa.gov](mailto:angulo.karen@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

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- 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 provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

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

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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-2006-0253 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 10, 2006.

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 your copies, identified by docket ID number EPA-HQ-OPP-2006-0253, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

**II. Background and Statutory Findings**

*A. What Action is the Agency Taking?*

In evaluating the tolerance exemption under 40 CFR 180.920 for “Mono- and

bis-(1H, 1H, 2H, 2H-perfluoroalkyl) phosphates where the alkyl group is even numbered and in the C<sub>6</sub>-C<sub>12</sub> range," EPA determined that there were potential risks of concern associated with the use of these perfluoroalkyl phosphates. EPA concluded that it was unable to determine that the tolerance exemption met the safety requirements of FFDCA section 408(c)(2) and proposed the revocation of the tolerance exemption in the **Federal Register** on April 19, 2006 (71 FR 20048) (FRL-8058-3).

EPA received comments on the proposed rule from Bayer CropScience and Mason Chemical Company. Neither commentator challenged EPA's conclusions on the chemical described under the current tolerance exemption. Therefore, this final rule revokes the tolerance exemption under 40 CFR 180.920 for "Mono- and bis-(1H, 1H, 2H, 2H-perfluoroalkyl) phosphates where the alkyl group is even numbered and in the C<sub>6</sub>-C<sub>12</sub> range" 18 months after the publication date of this final rule in the **Federal Register**. EPA's response to the comments received is found in the following section.

#### B. EPA's Responses to Comments

1. *Does the tolerance exemption name the wrong chemical?* Mason Chemical Company claims that the current tolerance exemption describes the wrong chemical, and this error reaches back to the establishment of the exemption. They assert that the tolerance exemption actually should encompass certain perfluoroalkylphosphonic and phosphonic acid compounds instead of the perfluoroalkyl phosphate compound described by the tolerance exemption.

The Agency disagrees. The current inert ingredient tolerance exemption under 40 CFR 180.920 for "Mono- and bis-(1H, 1H, 2H, 2H-perfluoroalkyl) phosphates where the alkyl group is even numbered and in the C<sub>6</sub>-C<sub>12</sub> range" was established on January 23, 1985 by a final rule published in the **Federal Register** (50 FR 2983). The Agency established this tolerance exemption in response to a petition from the American Hoechst Corporation. The petitioner requested that the new tolerance exemption limit the use of the compound in pesticide products to a defoaming agent used only on growing crops at no more than 0.5% of the pesticide formulation. No comments were received on the proposed rule. From the time of the establishment of the current tolerance exemption in 1985 until now, the Agency has received no petitions to modify the current tolerance exemption. The Agency concludes that

the tolerance exemption is not in error as the commentators assert, rather, it describes the chemical compound that the original petitioner requested. If commodities are sold or distributed containing pesticide residues that are not within the tolerance expression, and for which there is no existing tolerance or exemption, those commodities may be deemed adulterated for purposes of FFDCA.

2. *Reassess the compounds.* Mason Chemical Company asserts that EPA must reassess the perfluoroalkylphosphonic and phosphonic acid compounds because the current tolerance exemption should have included these chemicals all along.

FFDCA as amended by FQPA requires EPA to reassess all inert ingredient tolerance exemptions established prior to August 3, 1996. No inert ingredient tolerance exemption that includes the perfluoroalkylphosphonic and phosphonic acid compounds described by Mason Chemical Company was in existence prior to 1996, nor is one in existence now. EPA cannot reassess a tolerance exemption that does not exist.

3. *Permit use of the compounds.* Bayer CropScience requests that the Agency allow the use of the perfluoroalkylphosphonic and perfluoroalkylphosphonic acid compounds under the current exemption for two years. Bayer CropScience requested use of the compounds only for two years because "insufficient data exist for perfluoroalkylphosphonic and perfluoroalkylphosphonic acid to allow the Agency to make a safety finding according to FFDCA section 408(b)(2)." Bayer CropScience indicated an interest in generating data to support a new tolerance exemption for these compounds.

FFDCA requires a tolerance or tolerance exemption for all chemicals used in pesticide products. As of July 5, 2006, EPA has not received a petition for a tolerance or tolerance exemption for the perfluoroalkylphosphonic and perfluoroalkylphosphonic acid compounds, and data sufficient for evaluating these compounds have not been submitted to the Agency. As stated in the proposed rule, the Agency has identified human health and environmental risks of concern for the perfluoroalkyl phosphate chemical described by the current exemption under 40 CFR 180.920, and the FFDCA safety finding cannot be made. A party or parties may choose to petition the Agency for a tolerance or tolerance exemption for the perfluoroalkylphosphonic and perfluoroalkylphosphonic acid

compounds. The very limited information available to the Agency indicates that there may be serious human health and environmental risk issues associated with these compounds. It is likely that petitioner(s) will have to support their petition with a robust dataset.

#### C. What is the Agency's Authority for Taking this Action?

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, as amended by the FQPA of 1996, Public Law 104-170, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore "adulterated" under section 402(a) of FFDCA, 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce (21 U.S.C. 331(a)). For a food-use pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under FFDCA, but also must be registered under FIFRA (7 U.S.C. 136 *et seq.*). Food-use pesticides not registered in the United States must have tolerances in order for commodities treated with those pesticides to be imported into the United States.

#### D. When Do These Actions Become Effective?

This action becomes effective 18 months after the publication date of this final rule in the **Federal Register**. Any commodities listed in the regulatory text of this document that are treated with the pesticide chemical subject to this final rule, and that are in the channels of trade following the tolerance exemption revocations, shall be subject to FFDCA section 408(1)(5), as established by the FQPA. Under this section, any residue of the pesticide chemical in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

- The residue is present as the result of an application or use of the pesticide chemical at a time and in a manner that was lawful under FIFRA.
- The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under an exemption from tolerance. Evidence to show that food

was lawfully treated may include records that verify the dates that the pesticide chemical was applied to such food.

#### *E. What is the Contribution to Tolerance Reassessment?*

By law, EPA is required by August 2006, to reassess the tolerances and exemptions from tolerances that were in existence on August 2, 1996. This document revokes one inert ingredient tolerance exemption which is counted as a tolerance reassessment toward the August 2006, review deadline under FFDCA section 408(q), as amended by FQPA in 1996.

### III. Statutory and Executive Order Reviews

In this final rule, EPA is revoking a tolerance exemption established under section 408(d) of FFDCA. The Office of Management and Budget (OMB) has exempted this type of action from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this final rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether revocations of tolerances might significantly impact a substantial number of small entities and concluded that, as a general matter,

these actions do not impose a significant economic impact on a substantial number of small entities. This analysis was published on December 17, 1997 (62 FR 66020), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticide listed in this rule, the Agency hereby certifies that this final action will not have a significant economic impact on a substantial number of small entities. In a memorandum dated May 25, 2001, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation (this Agency document is available in the docket of this final rule). Furthermore, for the pesticide named in this final rule, the Agency knows of no extraordinary circumstances that exist as to the present revocations that would change the EPA's previous analysis (note also that revocation of these tolerances does not affect entities selling or distributing commodities containing only pesticide residues that are not subject to these tolerances). In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this final

rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This final rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this final rule.

### IV. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

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

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

Dated: July 26, 2006.

**Lois Rossi,**

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

■ Therefore, 40 CFR part 180 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. In § 180.920, the table is amended by revising the following inert ingredient to read as follows:

**§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * *	* *	
Mono- and bis-(1 <i>H</i> , 1 <i>H</i> , 2 <i>H</i> , 2 <i>H</i> -perfluoroalkyl) phosphates where the alkyl group is even numbered and in the C <sub>6</sub> -C <sub>12</sub> range.	Not more than 0.5% of pesticide formulation. Expires February 9, 2008.	Surfactant, related adjuvants of surfactants
* * *	* *	

[FR Doc. E6-12541 Filed 8-8-06; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0251; FRL-8082-2]

**Inert Ingredient; Revocation of the Tetrahydrofurfuryl Alcohol (THFA) Tolerance Exemption**

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

**ACTION:** Final rule.

**SUMMARY:** EPA is revoking, under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(e)(1), the existing exemption from the requirement of a tolerance for residues of the inert ingredient "Tetrahydrofurfuryl alcohol" (THFA) under 40 CFR 180.910, and establishes a limited tolerance for THFA under 40 CFR 180.1263. The regulatory action contributes toward the Agency's tolerance reassessment requirements under FFDCA section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required by August 2006 to reassess the tolerances that were in existence on August 2, 1996. This regulatory action counts as a tolerance reassessment toward the August 2006 review deadline.

**DATES:** This rule is effective February 9, 2008.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0251. All documents in the docket are listed in the index for the docket. 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

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