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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0582; FRL–8082–1]

Isophorone; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends existing exemption from the requirement of a tolerance for residues of isophorone (CAS Reg. No. 78–59–1) to limit the use to beets, ginseng, rice, spinach, sugar beets, and Swiss chard. The Isophorone Task Group (ITG) requested this revised exemption from the requirement of a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996. This regulatory action contributes toward the Agency's tolerance reassessment requirements under FFDCA section 408(q), as amended by the FQPA of 1996. By law, EPA is required by August 2006 to reassess the tolerances that were in existence on August 2, 1996. The regulatory action in this document pertains to the revision of one existing tolerance exemption which is counted as a tolerance reassessment toward the August 2006 review deadline.

DATES: This regulation is effective August 9, 2006. Objections and requests for hearings must be received on or before October 10, 2006, 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–2006–0582. 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 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8811; e;mail address: *leifer.kerry@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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**.

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

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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–2006–0582 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–2006–0582, 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 telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of April 27, 2005 (70 FR 7951) (FRL–7710–1), 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 4E6894) The Isophorone Task Group (ITG) of the Ketones Panel of the American Chemistry Council, 1300 Wilson Blvd., Arlington, VA 22209. The petition requested that 40 CFR 180.920 be amended by limiting the existing exemption from the requirement for isophorone (CAS Reg. No. 78–59–1) to rice, spinach, and sugar beets. That notice included a summary of the pesticide petition prepared by ITG, the petitioner. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.

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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for an exemption from the requirement of a tolerance for residues of isophorone in or on beets, ginseng, rice, spinach, sugar beets, and Swiss chard. EPA's assessment of exposures and risks associated with establishing the tolerance 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. The nature of the toxic effects caused by isophorone are discussed in the following Table 1 as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the reviewed toxicity studies.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents (rats)	NOAEL = 233.8/>311.8 milligram/kilogram/day (mg/kg/day) male/female.
		LOAEL = 102.5 (M)/not established (F) mg/kg/day based on M decrease in body weight
870.3150	90–Day oral toxicity study in nonrodents (dogs)	NOAEL = 150 mg/kg/day higest dose tested (HDT) LOAEL = cannot be established
870.3700	Prenatal developmental (inhalation) in rodents (mice)	Maternal NOAEL = 50 ppm LOAEL = 115 ppm based on decreased gestation day 18 body weight, corrected for uterine weight Developmental NOAEL = >115 ppm Developmental LOAEL = cannot be established
870.3700	Prenatal developmental (inhalation) in rodents (rats)	Maternal NOAEL = 25 ppm LOAEL = 50 ppm based on increased incidence of clinical signs (alopecia, ano-genital and cervical staining) Developmental NOAEL = 115 ppm HDT Developmental LOAEL = cannot be established
870.4200	Carcinogenicity (rats)	NOAEL = 250/500 mg/kg/day (M/F) LOAEL = 500 (M)/not established (F) based on M = increased incidence of preputial gland carcinoma
870.4200	Carcinogenicity (mice)	NOAEL = 500 mg/kg/day HDT LOAEL = cannot be established

Isophorone was evaluated as part of the International Programme on Chemical Safety (ICPS). The IPCS is a joint venture of the United Nations Environment Programme, the International Labour Organisation, and the World Health Organization. The main objective of the IPCS is to carry out and disseminate evaluations of the effects of chemicals on human health and the quality of the environment.

The ICPS Environmental Health Criteria monograph for isophorone critically evaluated the available toxicity data on isophorone, which included a consideration of the studies summarized in Table 1 as well as other available toxicity data on isophorone. As part of the human health risk assessment of isophorone, the ICPS monograph states that ''limited studies in rats and mice indicate that isophorone does not affect fertility nor does it cause developmental toxicity in experimental animals.'' Additionally in summarizing the results of genotoxicity testing, the ICPS further concluded that ''the weight of evidence of all mutagenicity data supports the contention that isophorone is not a potent DNA-reactive compound.''

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL are identified is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases.

A summary of the toxicological endpoints for isophorone used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ISOPHORONE FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic dietary (all populations). Special FQPA SF = 1 ..... cPAD = chronic RfD Special FQPA SF = 0.2 mg/kg/day	NOAEL = 150 mg/kg/day UF = 1.000 Chronic RfD = 0.2 mg/kg/day 90–Day oral dog toxicity study. No toxicity was seen at the HDT		
Cancer (oral, dermal, inhalation).	NOAEL = 250 mg/kg/day	NA	Increased incidence of preputial gland carcinomas in male rats Toxicology and Carcinogenesis Study of Isophorone in F344/N Rats
	Classification: Under the 1986 cancer classification scheme, isophorone was classified as Group C- Possible Human Carcinogen, with a linear low-dose extrapolation approach and a 3/4s interspecies scaling factor for human risk. The upper bound estimate of unit risk, Q_1* is 6.08 x 10^{-4} in human equivalents		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* An exemption from the requirement of a tolerances has been established (40 CFR 180.40 CFR site) for the residues of isophorone, in or on beet, ginseng, rice, spinach, sugar beet and Swiss chard commodities. Risk assessments were conducted by EPA to assess dietary exposures from isophorone in food as follows:

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.

Option 1. No such effects were identified in the toxicological studies for isophorone; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.—Option 2.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The assessment was based on a screening level dietary assessment that assumed residues of isophorone in beet, ginseng, rice, spinach, sugar beet and Swiss chard commodities corresponding to the highest established active ingredient tolerance level residues for those commodities and 100% crop treated. The highest established tolerance level active ingredient residue level is chosen as ''worst-case'' chronic exposure scenario as it would be highly unlikely that residues of isophorone in the above-listed crops would be at such levels.

iii. *Cancer.* The assessment assumed residues of isophorone in beet, ginseng, rice, spinach, sugar beet and Swiss chard commodities corresponding to the highest established active ingredient tolerance level residues for those commodities and 100% crop treated. The highest established tolerance level active ingredient residue level is chosen as ''worst-case'' cancer exposure scenario as it would be highly unlikely that residues of isophorone in the above-listed crops would be at such levels.

2. *Dietary exposure from drinking water.* Monitoring exposure data are utilized to complete a dietary exposure

analysis and risk assessment for isophorone in drinking water. The estimated drinking water concentration (EDWC) of isophorone of 10 µg/L utilized for the purposes of this tolerance action is a value equivalent to the highest measured concentration of isophorone in drinking water sources in monitoring studies used by EPA to establish ambient water quality criteria for isophorone. (EPA 440/5–80–056; NTIS PB81–11767).

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).

Since the use of isophorone is limited to pesticide productswhich are not registered for use on any sites that would result in residential exposure, no residential exposures are expected and a residential exposure assessment has not been conducted

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to isophorone and any other substances and isophorone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that isophorone has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased prenatal or postnatal susceptibility of isophorone following *in utero* exposure to rats and mice.

3. *Conclusion*. There is an adequate toxicity database for the selection of doses and endpoints for use in risk assessment for isophorone. Exposure data are complete or are estimated based on data that reasonably account for potential exposures. The use of the IRIS chronic reference dose (cRfD) utilizes an additional 10X UF beyond the traditional UFs for intraspecies variability and interspecies extrapolation of 100X . This is protective of any potential concerns for increased susceptibility of infants and children to isophorone. The additional 10X uncertainty factor incorporated into the IRIS RfD is based on the use of a subchronic toxicity study, which, given the lack of increased pre-natal and postnatal susceptibility of isophorone, would address any potential concerns for increased susceptibility of infants and children to isophorone, therefore the FQPA factor is removed.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. As there were no toxic effects attributable to a single dose, an endpoint of concern was not identified to quantitate acute dietary risk to the general population or to the subpopulation females 13-50 years old. No acute risk is expected from exposure to isophorone

2. *Chronic risk*. The chronic dietary exposure analysis is based on a screening level dietary assessment that assumed residues of isophorone in beets, ginseng, rice, spinach, sugar beet and Swiss chard commodities corresponding to the highest established active ingredient tolerance level residues for those commodities and 100% crop treated Even with these highly conservative assumptions, the risk estimates are well below the Agency's level of concern. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to isophorone from food and drinking water will utilize 1.8% of the chronic population adjusted dose (cPAD) for the U.S. population, and 4.4% of the cPAD for non-nursing infants, the most highly exposed population subgroup. Based on the use pattern, chronic residential exposure to residues of isophorone is not expected. Drinking water was incorporated directly into the dietary assessment using the concentration for drinking water given in unit III.C.2.

3. *Aggregate cancer risk for U.S. population*. A non-threshold (Q_1*) approach is used to estimate estimate cancer risk. The upper bound estimate of lifetime cancer risk for the U.S population is 2.14×10^{-6}. This value is derived by multiplying the upper bound estimate of unit risk, 6.08×10^{-4} by the chronic dietary exposure (food + drinking water) for the U.S. general population (0.003520 mg/kg/day). Drinking water was incorporated directly into the dietary assessment using the concentration for drinking water given in unit III.C.2. Since this upper bound estimate of cancer risk is based on a very conservative exposure estimate, and is within the range of one in one million cancer risk that is typically considered to not be a concern. EPA therefore concludes that isophorone is not expected to pose a carcinogenic risk to humans. If applicable, insert text. There is no boilerplate for this section.

4. *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, and to infants and children from aggregate exposure to isophorone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

There are currently no Codex Maximum Residue Limits for isophorone

C. Response to Comments

Ten comments were received regarding petition PP 4E6894. One comment, from B. Sachau, regarded general opposition to Agency approval of tolerances and exemptions other than zero, and general opposition to any residue left on a treated crop. The Agency finds that this comment contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to isophorone including all anticipated dietary exposures and other exposures for which there is reliable information. This comment, as well as prior similar comments from B. Sachau have been responded to by the Agency on several occasions. For example, (October 29, 2004, 69 FR 63083), (January 7, 2005, 70 FR 1349), and (June 30, 2005, 70 FR 37683. The other nine comments regarded the use of isophorone in desmedipham and phenmedipham formulations for use on beets, Swiss chard and ginseng. These uses are either part of existing section 24(c) registrations or section 18 emergency exemptions, with each of the commentors requesting that these commodities be included in the reassessment of the isophorone tolerance exemption. The Agency agrees that these commodities should be included in the tolerance exemption expression for isophorone and has included these commodities in the aggregate risk assessment and safety determination provided in Unit III.

V. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of the inert ingredient isophorone, in or on beets, ginseng, rice, spinach, sugar beets, and Swiss chard.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. 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 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: July 28, 2006.

Lois Rossi,

Director, 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 180.920 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.

[FR Doc. E6–12547 Filed 8–8–06; 8:45 am]

BILLING CODE 6560–50–S

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-(1*H*, 1*H*, 2*H*, 2*H*-perfluoroalkyl) Phosphates Where the Alkyl Group is Even Numbered and in the C_6-C_{12} 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-(1*H*, 1*H*, 2*H*, 2*H*-perfluoroalkyl) phosphates where the alkyl group is even numbered and in the C_6-C_{12} 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*.

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:

- 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 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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In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket 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 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