

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 the FFDCA, such as the exemption 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. The Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. 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 the 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.

#### X. 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: September 9, 2005.

**James Jones,**  
*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 180.1259 is added to subpart D to read as follows:

**§ 180.1259 *Reynoutria sachalinensis* extract; exemption from the requirement of a tolerance.**

Residues of the biochemical pesticide *Reynoutria sachalinensis* extract, when derived from the whole plant extract, are exempt from the requirement of a tolerance in or on all food commodities.

[FR Doc. 05-18725 Filed 9-20-05; 8:45 am]

**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-2005-0074; FRL-7736-2]

#### Iprovalicarb; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of Iprovalicarb in or on tomatoes. Bayer CropScience AG requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective September 21, 2005. Objections and requests for hearings must be received on or before November 21, 2005.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP-2005-0074. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This 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:** Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9354; e-mail address: [waller.mary@epa.gov](mailto:waller.mary@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 and Other Related Information?*

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

## II. Background and Statutory Findings

In the **Federal Register** of April 8, 2005 (70 FR 18001) (FRL-7703-8), 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 3E6578) by Bayer CropScience AG, 2 T.W. Alexander Drive; Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.581 be amended by establishing a tolerance for residues of the fungicide iprovalicarb, [1-methylethyl [(1S)-2-methyl-1-[[[1-(4-methylphenyl) ethyl] amino] carbonyl] propyl] carbamate], in or on tomatoes at 1.0 parts per million (ppm). That notice included a summary of the petition prepared by Bayer CropScience AG, the registrant. Comments were received on the notice of filing. EPA’s response to

these comments is discussed in Unit IV.C. below.

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 FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.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 a tolerance for residues of iprovalicarb on tomatoes at 1.0 ppm. 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. Specific information on the studies received and the nature of the toxic effects caused by iprovalicarb 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.epa.gov/edocket>.

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (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 lowest dose at which adverse effects of concern are identified (the LOAEL) 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 which 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. More information can be found on the general principles that EPA uses in risk characterization at <http://www.epa.gov/oppfead1/trac/science/>.

A summary of the toxicological endpoints for iprovalicarb used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of August 22, 2002 (67 FR 54351) (FRL-7194-3).

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* A tolerance has been established (40 CFR 180.581) for the residues of iprovalicarb, in or on grapes. Risk assessments were conducted by EPA to assess dietary exposures from iprovalicarb 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.

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

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), both of which incorporate food consumption data as

reported by respondents in the 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: Assessments were based on tolerance-level residues in/on grape commodities, anticipated residue (AR) values for tomato commodities, DEEM default processing factors, and 100% crop treated (100% CT) assumptions. The AR used for tomatoes was 0.5 ppm, or half the proposed tolerance level of 1.0 ppm for harmonization purposes.

iii. *Cancer.* The cancer dietary exposure analysis was based on the same assumptions as the chronic dietary exposure analysis.

iv. *Anticipated residue and percent crop treated (PCT) information.*

Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water.* There is no expectation that exposure to iprovalicarb residues would occur via drinking water. This action is for a tolerance on imported tomatoes only, and there are no registered uses of iprovalicarb in the United States.

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). Iprovalicarb is not registered for use on any sites that would result in residential exposure.

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.”

Although iprovalicarb is a carbamate compound, it is not a member of the class of insecticides known as the N-methyl carbamates for which the Agency is presently conducting a cumulative risk assessment. The common mechanism determination for the N-methyl carbamates was based on shared structural characteristics and their shared ability to cause neurotoxicity through the inhibition of acetylcholinesterase (AChE) by carbamylation of the serine hydroxyl group located in the active site of the enzyme. Iprovalicarb does not fit these characteristics and therefore should not be included in the N-methyl carbamate common mechanism group nor should it be included in the N-methyl carbamate cumulative risk assessment. The Agency has concluded that other subgroups of carbamates do not share a common mechanism of toxicity. 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 margin of exposure 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 is no evidence for increased susceptibility of fetuses to *in utero* exposure to iprovalicarb in either the rat developmental or rabbit developmental studies. There is qualitative evidence of susceptibility in the multi-generation reproduction study in the rat. However, it was concluded that there is a low degree of concern (and no residual uncertainty) for the effects seen because:

i. The increased susceptibility (decrease in pup survival) was seen only at the highest dose tested (2,074 milligram/kilogram/day (mg/kg/day)) which is twice the limit dose.

ii. The decrease in pup survival was seen only in 1-generation (F1, not replicated in F2).

iii. There are clearly defined NOAELs/LOAELs for parental and offspring toxicity.

iv. The effects seen in the offspring occurred at a much higher dose (192 mg/kg/day) than that used to establish the Chronic RfD (NOAEL of 2.62 mg/kg/day). Furthermore, the Agency concluded that a developmental neurotoxicity study is not required. No treatment-related toxicologically significant sign of neurotoxicity were observed in any available studies on iprovalicarb.

3. *Conclusion.* There is a complete toxicity data base for iprovalicarb and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Additionally the Agency concludes that there are reliable data that indicate there are no (residual) concerns for the prenatal and/or postnatal toxicity following exposure to iprovalicarb. Therefore, no additional safety factor (1X) is necessary to protect the safety of infants and children.

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

1. *Acute risk.* An endpoint attributable to a single dose was not identified for any population subgroups. Therefore, no acute risk is expected.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to iprovalicarb from food will utilize 8.4% of the cPAD for the U.S. population, [9.9 %] of the cPAD for all infants (< 1 year), and 37% of the cPAD for children (1-2 years). There are no residential uses for iprovalicarb that result in chronic residential exposure to iprovalicarb. In addition, there is no potential for chronic dietary exposure to iprovalicarb in drinking water. EPA does not expect the aggregate exposure (dietary only) to exceed 100% of the cPAD, as shown in Table of this unit:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO IPROVALICARB

Population/Subgroup	cPAD (mg/kg/day)	% cPAD (Food)
U.S. population	0.026	8.4
All Infants (< 1 yr)	0.026	9.9
Children 1-2 yrs	0.026	37

3. *Short-term risk.* Iprovalicarb is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Iprovalicarb is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* The lifetime cancer risk from iprovalicarb dietary exposure is determined for the U.S. population (total) only. The estimated exposure to iprovalicarb is 0.002189 mg/kg/day. Applying the Q1\* of  $4.47 \times 10^{-4}$  (mg/kg/day)<sup>-1</sup> to the exposure value results in a cancer risk estimate of  $9.74 \times 10^{-7}$ . This risk is negligible, and does not exceed the Agency's level of concern.

6. *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 iprovalicarb residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (HLPC/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

Iprovalicarb is not in the Codex system. There are no MRLs in Mexico. The Agency is recommending a 1.0 ppm tolerance on tomatoes in order to harmonize with the existing 1.0 mg/kg provisional maximum residue limit (MRL) for iprovalicarb on tomatoes in the European Union.

##### C. Response to Comments

Comments were received from a private citizen on April 17, 2005

objecting to the sale and use of this product. The comments further stated that no long term or combined tests have been done to show complete safety. The Agency response is as follows: The petitioner did not request registration of iprovalicarb in the U.S. The petitioner is seeking an import tolerance which would allow tomatoes treated in foreign countries to be imported into the U.S. The U.S. cannot regulate the sale and the use of a pesticide in a foreign country. The Agency had sufficient data, including chronic, long-term data, to support a determination that there is reasonable certainty that no harm will result from dietary exposure to residues of iprovalicarb.

#### V. Conclusion

Therefore, the tolerance is established for residues of iprovalicarb, [[1-methylethyl [(1S)-2-methyl-1-[[[1-(4-methylphenyl) ethyl] amino] carbonyl] propyl carbamate, in or on tomatoes at 1.0 ppm.

#### VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

##### A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2005-0074 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 November 21, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14<sup>th</sup> St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2005-0074, to: Public Information

and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in ADDRESSES. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

*B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

**VII. 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.

**VIII. 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: September 12, 2005.

**Meredith F. Laws,**

*Acting 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 180.581 is amended by alphabetically adding “tomatoes” in the table in paragraph (a) and by revising footnote 1 to read as follows:

**§ 180.581 lprovalicarb; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * *	* *
Tomatoes <sup>1</sup> .....	1.0

<sup>1</sup>There is no U.S. registration as of September 1, 2005.

\* \* \* \* \*

[FR Doc. 05-18828 Filed 9-20-05; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-2004-0246; FRL-7734-3]

#### Lindane; Tolerance Actions

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

**ACTION:** Final rule.

**SUMMARY:** EPA is revoking specific existing tolerances for the insecticide lindane because, following receipt of registrant requests, the Agency canceled their associated Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registrations in the United States.

**DATES:** This regulation is effective September 21, 2005. However, certain regulatory actions will not occur until the date specified in the regulatory text. Objections and requests for hearings must be received on or before November 21, 2005.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit IV. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP-2004-0246. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This 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:** Joseph Nevola, Special Review and

Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8037; e-mail address: [nevola.joseph@epa.gov](mailto:nevola.joseph@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

##### II. Background

###### A. What Action is the Agency Taking?

In the **Federal Register** of April 15, 2005 (70 FR 20035) (FRL-7702-2), EPA proposed to revoke certain tolerances

for residues of the insecticide lindane. Also, the proposal of April 15, 2005, provided a 60-day comment period which invited public comment for consideration and for support of tolerance retention under the Federal Food, Drug, and Cosmetic Act (FFDCA) standards.

The tolerances revoked in this final rule are no longer necessary to cover residues of the relevant pesticide in or on domestically treated commodities or commodities treated outside but imported into the United States. It is EPA's general practice to revoke those tolerances and tolerance exemptions for residues of pesticide active ingredients on crop uses for which there are no active registrations under FIFRA, unless any person in comments on the proposal indicates a need for the tolerance or tolerance exemption to cover residues in or on imported commodities or domestic commodities legally treated.

EPA has historically been concerned that retention of tolerances that are not necessary to cover residues in or on legally treated foods may encourage misuse of pesticides within the United States. Thus, it is EPA's policy to issue a final rule revoking those tolerances for residues of pesticide chemicals for which there are no active registrations under FIFRA, unless any person commenting on the proposal demonstrates a need for the tolerance to cover residues in or on imported commodities or domestic commodities legally treated.

Generally, EPA will proceed with the revocation of these tolerances on the grounds discussed in Unit II.A. if one of the following conditions applies:

1. Prior to EPA's issuance of a section 408(f) order requesting additional data or issuance of a section 408(d) or (e) order revoking the tolerances on other grounds, commenters retract the comment identifying a need for the tolerance to be retained.

2. EPA independently verifies that the tolerance is no longer needed.

3. The tolerance is not supported by data that demonstrate that the tolerance meets the requirements under FQPA.

Today's final rule does not revoke those tolerances for which EPA received comments stating a need for the tolerance to be retained. In response to the proposal published in the **Federal Register** of April 15, 2005 (70 FR 20035), EPA received comments during the 60-day public comment period, as follows:

*Comments by private citizens.* One private citizen stated that all lindane tolerances should be revoked. Another private citizen expressed a general