

*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 as required by 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 other 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 104-13, 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 pesticides listed in this rule, the Agency hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Specifically, as per the 1997 notice, EPA has reviewed its available data on imports and foreign pesticide usage and concludes that there is a reasonable international supply of food not treated with canceled pesticides. Furthermore, for the pesticides named in this final rule, the Agency knows of no extraordinary circumstances that exist as to the present revocations that would change EPA's previous analysis. 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 FFDCFA. 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.

#### VI. 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 180.144 is amended by revising the table under paragraph (a) to read as follows:

#### § 180.144 Cyhexatin; tolerances for residues.

(a) *General.* \* \* \*

Commodity	Parts per million	Expiration/Revocation Date
Orange, juice	0.1	6/13/09

\* \* \* \* \*

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-2005-0221; FRL-7730-3]

#### Reynoutria Sachalinensis Extract; Exemption from the Requirement of a Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide *Reynoutria sachalinensis* extract on all food commodities. The Interregional Research Project Number 4 (IR-4), on behalf of KHH Bioscience, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA),

requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Reynoutria sachalinensis* extract.

**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 VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP-2005-0221. 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:** Driss Benmhend, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9525; e-mail address: [benmhend.driss@epa.gov](mailto:benmhend.driss@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. 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 March 31, 2004 (69 FR 16925) (FRL-7342-4), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 3E6751) by Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, 681 U.S. Highway 1 South, North Brunswick, NJ 08902-3390, on behalf of KHH BioScience Inc., 920 Campus Drive, Suite 101, Raleigh, NC 27606. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Reynoutria sachalinensis* extract. This notice included a summary of the petition prepared by the petitioner IR-4, on behalf of KHH BioScience Inc. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of the 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. Pursuant to section 408(c)(2)(B), in establishing or

maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require 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...." Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

##### **III. Toxicological Profile**

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information 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.

*Reynoutria sachalinensis* is a naturally-occurring plant in the environment, commonly known as Giant knotweed. It is a rhizomatous, herbaceous, perennial, terrestrial plant belonging to the *Polygonaceae* family. The plant is a native of East Asia, but was introduced into Europe and North America in the 19th century as a fodder plant for cattle and as an ornamental. *Reynoutria sachalinensis* has a wide geographic distribution throughout the United States, Europe, and Asia. The plant is currently present in 25 U.S. States (Alaska, California, Connecticut, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Montana, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, Washington, West Virginia and Wisconsin). It is found in diverse habitats including riparian areas, wet meadows, floodplain forests, forest edges, roadsides, railroad and utility rights-of way, and open areas. The plant has become invasive in

certain regions. According to the Invasive Plant Atlas of New England, this weed is present in all of the northeast U.S., with the exception of New Hampshire, as far south as North Carolina and Tennessee. It has also been reported in Louisiana, Montana, Idaho, Alaska, and three west coast States.

*Reynoutria sachalinensis* extract is an ethanolic extract of dried, ground *Reynoutria sachalinensis* plants, and is already approved as an active ingredient by EPA for use as a spray on non-food, ornamental plants grown in greenhouses. The active ingredient has been used in this manner for over 4 years with no reports of harmful health effects to greenhouse workers. In addition, there is a long history of human dermal and oral exposure to *Reynoutria sachalinensis* through its use as an ornamental plant, as a human medicinal agent, and as human food. Humans are regularly, physically exposed to the plant when handling it as an ornamental and there have been no known reports of any adverse health effects to humans via physical contact with the plant. In Asian folk medicine, the rhizomes, leaves, and stems of the plant have been used as a laxative,

diuretic, and for the treatment of dermatitis and athlete's foot. *Reynoutria sachalinensis* has been consumed in the human diet in Japan for generations without any known negative effects. The plant is sold commercially in Japanese supermarkets for use in soups, as a deep-fried vegetable, and as a vinegared side dish. *Reynoutria sachalinensis* is also a floral nectar source for European honey bees, and thus many more humans are already indirectly exposed to the active ingredient via consumption of honey. The active ingredient has been registered and used in two end use products in Germany (Milsana fluessig and Milsana Pulver) as a resistance enhancer on fruit and vegetables since November 2000. To date, there have been no reports of adverse health effects resulting from the use of *Reynoutria sachalinensis* on food.

This final rule supports the use of *Reynoutria sachalinensis* extract as the active ingredient in an end-use product that will be used on food crops to enhance the resistance to fungal and bacterial diseases.

Acute toxicity studies were previously submitted and reviewed by EPA in support of the registrations of

the manufacturing-use product, *Reynoutria sachalinensis* Bioprotectant, and the greenhouse, non-food-use end-use product, Milsana® Bioprotectant Concentrate. Submitted data for the technical grade active ingredient (TGAI) and the end-use product, indicate Toxicity Category IV for acute oral and acute inhalation toxicity. Acute dermal toxicity data indicated a Toxicity Category III. The data reported for primary eye irritation studies showed that the test substance was moderately irritating, and was given a Toxicity Category III when the TGAI was used, and Toxicity Category II when the end-use product Milsana® is used as a test material. Exposure to Milsana® produced very slight erythema in animal tests; as a result, a Toxicity Category IV was given for dermal irritation.

The Agency deemed the submitted acute toxicity studies acceptable and approved the bridging of these studies to support this tolerance exemption. A summary of these acute toxicity studies is presented in the table below.

#### ACUTE TOXICITY DATA FOR REYNOUTRIA SACHALINENSIS

Data Requirement	Results	Toxicity Category	MRID No.
Acute oral toxicity	TGAI: Lethal dose (LD) <sub>50</sub> > 5,000 milligrams/kilogram (mg/kg) EP: LD <sub>50</sub> > 5,000 mg/kg	IV	448219-04
		IV	448219-05
Acute dermal toxicity	TGAI: LD <sub>50</sub> > 2,000 mg/kg EP: LD <sub>50</sub> > 5,000 mg/kg	III	448219-06
		III	448219-07
Acute inhalation toxicity	EP: Lethal concentration (LC) <sub>50</sub> > 2.6 mg/liter (L)	IV	448219-08
Primary eye irritation	TGAI: Slight irritant EP: Moderate irritant	III	448219-09
		II	448219-10
Primary dermal irritation	EP: No dermal irritation symptoms up to 72-hour post-dosing	IV	448219-11
Skin sensitization	TGAI: Buehler test was negative EP: Buehler test was negative	Not a sensitizer	448219-13
		Not a sensitizer	448219-14

Additionally, data waivers were requested by the applicant for the following Tier I toxicology data requirements:

1. Genotoxicity
2. Teratogenicity
3. Immune Response
4. 90-day Feeding
5. 90-day Dermal
6. 90-day Inhalation

The Agency granted these waivers based on the widespread and regular exposure that humans already have to *Reynoutria sachalinensis* in the

environment, in food and medicine, and as an ornamental plant. As stated previously, large numbers of humans have been and continue to be regularly exposed to the active ingredient via physical contact and in their diet with no known reports of adverse effects. In addition, researchers, manufacturers, and others who work with this active ingredient have not reported any adverse health effects. Thus, the Agency does not expect the use of *Reynoutria sachalinensis* extract on food crops to result in any harmful effects to humans.

*Reynoutria sachalinensis* contains anthraquinones, which are widespread in plants, including plants used for human consumption. Most of the total anthraquinone content in plants consists of physcion, emodin, and chrysophanol. *Reynoutria sachalinensis* contains both emodin and physcion. While physcion and chrysophanol have shown no genotoxic effects, emodin has been shown to have genotoxic potential when extracted from edible plant substrates (e.g., beans, peas, cabbage, lettuce, plaintain, buckwheat). However,

whole plant extracts containing these anthraquinones have been shown not to be genotoxic, and to have properties that counteract genotoxic anthraquinones. Therefore, because the *Reynoutria sachalinensis* extract is derived from the whole plant extract, the Agency has concluded that *Reynoutria sachalinensis* extract does not present a genotoxicity risk.

#### IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

##### A. Dietary Exposure

1. *Food.* The Agency is not concerned about dietary exposure to *Reynoutria sachalinensis* because large numbers of humans have consumed it regularly without any reports of adverse effects. In Japan, *Reynoutria sachalinensis* is commonly used as a vegetable and is a known source of vitamins A, C, and E. Young shoots are edible and are harvested to be used in soups, as a deep-fried vegetable, a vinegared side dish, and sometimes mixed with tobacco or used as a substitute for it. *Reynoutria sachalinensis* is sold commercially in Japanese supermarkets for use as human food. *Reynoutria sachalinensis* is listed among floral nectar sources for European honey bees; therefore, humans are indirectly exposed to the active ingredient via consumption of honey.

In any event, negligible to no risk is expected for the general populations, including infants and children, because oral toxicity tests on *Reynoutria sachalinensis* indicated that the extract is non-toxic (Toxicity Category IV), thus, the risks are considered minimal.

With regard to the emodin content of *Reynoutria sachalinensis* extract, the Agency is not concerned about dietary exposure because *Reynoutria sachalinensis* extract is derived from the whole plant extract, which is not genotoxic.

2. *Drinking water exposure.* *Reynoutria sachalinensis* commonly grows along rivers and streams in much of the United States. The leaves of *Reynoutria sachalinensis* are killed off in frosts and leaf litter naturally drops into nearby bodies of water; therefore, those water bodies are already exposed to exudates of this plant. In those areas, the use of *Reynoutria sachalinensis*

extract is unlikely to result in additional residues to drinking water that are above pre-existing levels. In other areas where the *Reynoutria sachalinensis* plant does not already exist, the Agency is not concerned about drinking water exposure because it is non-toxic and studies involving feeding of the active ingredient in acute oral rat trials indicated no adverse effect.

##### B. Other Non-Occupational Exposure

*Reynoutria sachalinensis* is a naturally-occurring plant currently found in 25 U.S. States as an ornamental plant, an invasive weed, and a grazing crop. Many humans are already regularly exposed to the plant in the environment. In certain areas of the world, i.e., Japan, Germany, and parts of Europe, the plant is consumed directly and indirectly as human food and is used as a pesticide on food. There have been no reported adverse effects to *Reynoutria sachalinensis*.

1. *Dermal exposure.* There is a long history of human dermal exposure to *Reynoutria sachalinensis* as it is a widespread, naturally-occurring plant in the environment. Humans have had direct contact with the plant through its use as an ornamental, and greenhouse workers have been exposed to *Reynoutria sachalinensis* extract when applying the EPA registered product Milsana® Bioprotectant to ornamentals. There have been no reported adverse effects to humans from the aforementioned forms of exposure. In addition, results of the acute dermal study indicated low toxicity (Toxicity Category III) and no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are considered minimal.

2. *Inhalation exposure.* As stated above, there have been no reported harmful effects to humans from exposure to *Reynoutria sachalinensis* in the environment, from its use as an ornamental, or from the application of *Reynoutria sachalinensis* extract to non-food crops in greenhouses. Furthermore, the inhalation toxicity studies showed no toxicity (Toxicity Category IV), thus the risks anticipated for this route of exposure are considered minimal.

#### V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish an exemption from 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." These

considerations include the possible cumulative effects of such residues on infants and children.

Common mechanisms of toxicity are not relevant to a consideration of cumulative exposure to *Reynoutria sachalinensis* extract because the extract is not toxic to mammalian systems. Thus, the Agency does not expect any cumulative or incremental effects from exposure to residues of *Reynoutria sachalinensis* extract when applied/used as directed on the label and in accordance with good agricultural practices.

#### VI. Determination of Safety for U.S. Population, Infants and Children

##### A. U.S. population

There is reasonable certainty that no harm will result from aggregate exposure to residues of *Reynoutria sachalinensis* extract to the U.S. population, infants, and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the fact that the plant is a part of the human diet in certain areas of the world with no reported adverse effects, and that humans have had frequent physical contact with *Reynoutria sachalinensis* and plants treated with *Reynoutria sachalinensis* extract with no negative health effects. In addition, the Toxicity Category IV for acute oral toxicity indicates that the extract is non-toxic. Finally, the Agency has concluded that there is a reasonable certainty of no harm when the *Reynoutria sachalinensis* extract is derived from the whole plant extract.

##### B. Infants and children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (also referred to as a margin of safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of exposure will be safe for infants and children. Margins of exposure are often referred to as uncertainty or safety factors. In this instance, based on all available information, the Agency concludes that *Reynoutria sachalinensis* extract is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children and adults when *Reynoutria sachalinensis* extract is used as labeled, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure approach to assess

the safety of *Reynoutria sachalinensis* extract.

## VII. Other Considerations

### A. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCFA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.”

*Reynoutria sachalinensis* extract is not a known endocrine disruptor nor is it related to any class of known endocrine disruptors. Thus, there is no impact via endocrine-related effects on the Agency’s safety finding set forth in this final rule for *Reynoutria sachalinensis* extract.

### B. Analytical Method(s)

Through this action, the Agency proposes to establish an exemption from the requirement of a tolerance for the extract of *Reynoutria sachalinensis* when used on fruit and vegetable crops. For the very same reasons that support the granting of this tolerance exemption, the Agency has concluded that an analytical method is not required for enforcement purposes for these proposed uses of *Reynoutria sachalinensis* extract.

### C. Codex Maximum Residue Level

There are no codex maximum residue levels established for *Reynoutria sachalinensis* extract.

## VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCFA, 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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCFA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCFA 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 the FFDCFA, as was provided in the old sections 408 and 409 of the FFDCFA. 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-2005-0221 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 issues(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 14th 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 IX.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-2005-0221, to: Public Information and Records Integrity Branch, Information Resources and Services 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

## IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCFA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this 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 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