ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0160; FRL–7732–8]

Cyhexatin; Tolerance Actions

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), all existing tolerances for residues of the insecticide/acaricide cyhexatin because they do not meet requirements of FFDCA section 408(b)(2). EPA canceled food use registrations for cyhexatin in 1989. Currently, EPA determined that acute dietary risks from use of cyhexatin on commodities for which import tolerances exist exceed the Agency's level of concern. However, EPA also determined that if the only cyhexatin tolerance is for orange juice, there is a reasonable certainty that no harm to any population subgroup will result from exposure to cyhexatin treated oranges. Because manufacturers support a cyhexatin tolerance on orange juice for purposes of importation and the Agency has made a determination of safety for such a tolerance, EPA is establishing, concurrent with the revocation of the citrus fruit group tolerance, an individual time-limited tolerance on orange juice. The regulatory actions in this document contribute toward the Agency's tolerance reassessment requirements of the 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 in existence on August 2, 1996. The regulatory actions in this document pertain to the revocation of 41 tolerances which count as tolerance reassessments toward the August, 2006 review deadline.

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 requestfollow 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–2005–0160. 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*.

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 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 July 27, 2005 (70 FR 43368) (FRL–7723–5), EPA issued a proposed rule to revoke all existing tolerances for residues of the insecticide/acaricide cyhexatin and establish a time-limited tolerance on orange juice. Also, the proposal of July 27, 2005 provided a 30–day comment period which invited public comment.

In response to the proposal published in the **Federal Register** of July 27, 2005 (70 FR 43368), EPA received two comments during the 30–day public comment period, as follows:

Comments by private citizens. A private citizen stated opposition to the sale and use of cyhexatin, and stated that cyhexatin tolerances should not be extended for use on any food commodity. Another private citizen asked whether the final rule actions would mean that any amount of cyhexatin could be used on imported foods.

Agency response. Recently, EPA completed its Tolerance Reassessment Eligibility Decision (TRED) for cyhexatin. In the *Federal Register* of July 13, 2005 (70 FR 40341) (FRL–7720–3), EPA published a decision notice for the cyhexatin TRED. The TRED and documents in support of the TRED are available in Edocket ID number OPP–2004–0295 at *http://www.epa.gov/edocket*, and at *http://www.epa.gov/pesticides/reregistration/status.htm*. Because there are no active U.S. registrations, human exposure to this pesticide is strictly through the consumption of treated imported foods. Residential and occupational exposures as well as dietary exposure through drinking water are not expected because there is no domestic use of cyhexatin.

Because there have been no active U.S. registrations for cyhexatin since 1989, the comment on its sale and use is not relevant to this rulemaking. However, cyhexatin tolerances were maintained for purposes of importation. The commenters did not address EPA's determination that acute dietary

exposure estimates for cyhexatin and orange juice only are below the Agency's level of concern for all population subgroups and that a time-limited import tolerance for orange juice should be established. The commenters did not refer to any scientific studies or specific data that should be considered by the Agency.

EPA determined that acute dietary risks from use of cyhexatin on commodities for which import tolerances exist exceed the Agency's level of concern. Therefore, manufacturers had indicated that they would support only the import tolerances for apple (fresh, juice, sauce, and dried) and citrus (orange juice). However, the estimated acute dietary risks from use of cyhexatin on these commodities exceed the Agency's level of concern. The assessment concluded that for apples and oranges, the acute dietary exposure estimate for children 1-2 years of age is at 223% of the acute population-adjusted dose (aPAD) at the 99.9th percentile; for all infants < 1–year of age at 187% of the aPAD, and for children 3-5 years of age at 151% of the aPAD. Apple juice and apple sauces were the risk drivers.

Because of this acute dietary concern, manufacturers have withdrawn support for cyhexatin tolerances, except for orange juice. EPA has evaluated the dietary risks from the importation of orange juice concentrate to be processed into orange juice and has determined that there is reasonable certainty that no harm to any population subgroup will result from exposure to cyhexatin treated oranges. The acute dietary exposure estimates for orange juice only are below the Agency's level of concern for all population subgroups. The most highly exposed sub-population was children 1-2 years of age, at 35% of the aPAD.

Therefore, EPA is revoking all existing tolerances for residues of the insecticide/acaricide cyhexatin under FFDCA section 408(e)(1) because existing tolerances do not meet requirements of FFDCA section 408(b)(2).

Specifically, EPA is revoking the tolerances in 40 CFR 180.144 for combined residues of cyhexatin and its organotin metabolites (calculated as cyhexatin) in or on the following food commodities: Almond; almond, hulls; apple; cattle, fat; cattle, kidney; cattle, liver; cattle, meat byproducts, except kidney and liver; cattle, meat; citrus, dried pulp; fruit, citrus; goat, fat; goat, kidney; goat, liver; goat, meat byproducts, except kidney and liver; goat, meat; hog, fat; hog, kidney; hog, liver; hog, meat byproducts, except kidney and liver; hog, meat; hop; hop, dried cone; horse, fat; horse, kidney; horse, liver; horse, meat byproducts, except kidney and liver; horse, meat; milk, fat (=N in whole milk); nectarine; nut, macadamia; peach; pear; plum, prune, dried; plum, prune, fresh; sheep, fat; sheep, kidney; sheep, liver; sheep, meat byproducts, except kidney and liver; sheep, meat; strawberry; and walnut.

However, concurrent with the revocation of the crop group tolerance on fruit, citrus in 40 CFR 180.144 at 2 parts per million (ppm), a tolerance on orange juice should be established at 0.1 ppm. Available processing data indicate that cyhexatin residues of concern in orange juice concentrate were less than the limit of quantitation; i.e., less than 0.1 ppm. Nevertheless, additional generic data is needed for EPA to confirm processing, analytical method, and toxicological data. Under FFDCA section 408(f), if the Agency determines that additional information is reasonably required to support the continuation of a tolerance, EPA may require that parties interested in maintaining the tolerance provide the necessary information. Therefore, EPA is establishing an individual time-limited tolerance in 40 CFR 180.144 for combined residues of cyhexatin and its organotin metabolites (calculated as cyhexatin) in orange, juice at 0.1 ppm with an expiration/revocation date of June 13, 2009; i.e., the time-limited tolerance will be established for a period of 4 years from the TRED completion date of June 13, 2005 in order to allow sufficient time for the Agency to issue a data call-in request, the manufacturers to submit the needed data, and for the Agency to review it. After reviewing the available data, EPA will decide whether there is sufficient data to support the orange juice tolerance as a permanent one. If the requisite information is not submitted, EPA may issue an order revoking the tolerance at issue or allow the time-limited tolerance to expire.

Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore ''adulterated'' under section 402(a) of the FFDCA (21 U.S.C. 342(a)). Such food may not be distributed in interstate commerce (21 U.S.C. 331(a)). Food-use pesticides not registered in the United States must have tolerances in order for commodities treated with those pesticides to be imported into the United States.

A printed copy of the cyhexatin TRED may be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), P.O. Box 42419, Cincinnati, OH 45242–2419, telephone 1–800–490–9198; fax 1–513–489–8695; internet at *http://www.epa.gov/ncepihom/* and from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1–800–553–6847 or (703) 605–6000; internet at *http://www.ntis.gov/*. An electronic copy of the cyhexatin TRED is available on the internet at *http://www.epa.gov/pesticides/reregistration/status.htm*.

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

EPA's general practice is to revoke tolerances for residues of pesticide active ingredients on crops for which FIFRA registrations no longer exist and on which the pesticide may therefore, no longer be used in the United States. 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. Nonetheless, EPA will establish and maintain tolerances even when corresponding domestic uses are canceled if the tolerances, which EPA refers to as ''import tolerances,'' are necessary to allow importation into the United States of food containing such pesticide residues. However, where there are no imported commodities that require these import tolerances, the Agency believes it is appropriate to revoke tolerances for unregistered pesticides in order to prevent potential misuse.

C. When Do These Actions Become Effective?

EPA is revoking specific cyhexatin tolerances and establishing a time-limited tolerance on orange juice effective on the date of publication of this final rule in the **Federal Register**.

Any commodities listed in the regulatory text of this document that are treated with the pesticides subject to this final rule, and that are in the channels of trade following the tolerance revocations, shall be subject to FFDCA section 408(1)(5), as established by the FQPA. Under this section, any residues of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration (FDA) that: (1) The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and (2) the residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance

or exemption from tolerance. Evidence to show that food was lawfully treated may include records that verify the dates that the pesticide was applied to such food.

D. What is the Contribution to Tolerance Reassessment?

By law, EPA is required by August 2006 to reassess the tolerances in existence on August 2, 1996. As of September 6, 2005, EPA has reassessed over 7,430 tolerances. This document revokes a total of 41 tolerances which are counted as tolerance reassessments toward the August 2006 review deadline of FFDCA section 408(q), as amended by FQPA in 1996. For counting purposes, the Agency counts the citrus fruit group tolerance as one revocation (where a time-limited tolerance on orange juice is established in its place).

III. Are There Any International Trade Issues Raised by this Final Action?

EPA is working to ensure that the U.S. tolerance reassessment program under FQPA does not disrupt international trade. EPA considers Codex Maximum Residue Limits (MRLs) in setting U.S. tolerances and in reassessing them. MRLs are established by the Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. When possible, EPA seeks to harmonize U.S. tolerances with Codex MRLs. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain in a **Federal Register** document the reasons for departing from the Codex level. EPA's effort to harmonize with Codex MRLs is summarized in the tolerance reassessment section of individual REDs. EPA has developed guidance concerning submissions for import tolerance support of June 1, 2000 (65 FR 35069) (FRL–6559–3). This guidance will be made available to interested persons. Electronic copies are available on the internet at *http://www.epa.gov/*. On the Home Page select ''Laws and Regulations,'' then select ''Regulations and Proposed Rules'' and then look up the entry for this document under ''**Federal Register**—Environmental Documents.'' You can also go directly to the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

IV. 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–2005–0160 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 IV.A.1., 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–2005–0160, 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).

V. Statutory and Executive Order Reviews

In this final rule EPA revokes specific tolerances established under FFDCA section 408. The Office of Management and Budget (OMB) has exempted this type of action (i.e., a tolerance revocation for which extraordinary circumstances do not exist) 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 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 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.

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

* * * * *

[FR Doc. 05–18581 Filed 9–20–05; 8:45 am]

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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),