

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0246; FRL-7702-2]

Lindane; Proposed Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revoke 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.

DATES: Comments must be received on or before June 14, 2005.

ADDRESSES: Submit your comments, identified by docket identification (ID) number OPP-2004-0246, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov/>. Follow the on-line instructions for submitting comments.

- *Agency Web site:* <http://www.epa.gov/edocket/>. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

- *E-mail:* Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID number OPP-2004-0246.

- *Mail:* Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: docket ID number OPP-2004-0246.

- *Hand Delivery:* Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP-2004-0246. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number OPP-2004-0246. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at <http://www.epa.gov/edocket/>, including any personal information provided, unless the comment includes information claimed to be Confidential Business

Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, [regulations.gov](http://www.regulations.gov), or e-mail. The EPA EDOCKET and the [regulations.gov](http://www.regulations.gov) websites are "anonymous access" systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL-7181-7).

Docket: 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)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II.A. 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/>.

C. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, [regulations.gov](http://www.regulations.gov), or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in

accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the rulemaking by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns, and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

D. What Can I do if I Wish the Agency To Maintain a Tolerance That the Agency Proposes To Revoke?

This proposed rule provides a comment period of 60 days for any person to state an interest in retaining a tolerance proposed for revocation. If EPA receives a comment within the 60 day period to that effect, EPA will not proceed to revoke the tolerance immediately. However, EPA will take steps to ensure the submission of any needed supporting data and will issue an order in the **Federal Register** under FFDCA section 408(f) if needed. The order would specify data needed and the time frames for its submission, and would require that within 90 days some person or persons notify EPA that they will submit the data. If the data are not submitted as required in the order, EPA will take appropriate action under FFDCA. EPA issues a final rule after considering comments that are submitted in response to this proposed rule. In addition to submitting comments in response to this proposal, you may also submit an objection at the time of the final rule. If you fail to file an objection to the final rule within the time period specified, you will have waived the right to raise any issues resolved in the final rule. After the specified time, issues resolved in the

final rule cannot be raised again in any subsequent proceedings.

II. Background

A. What Action is the Agency Taking?

EPA is proposing to revoke specific existing tolerances for residues of the insecticide lindane in or on commodities listed in the regulatory text. EPA is proposing these tolerance actions to implement the tolerance recommendations made during the reregistration and tolerance reassessment processes (including follow-up on canceled or additional uses of pesticides). As part of the reregistration and tolerance reassessment processes, EPA is required to determine whether each of the amended tolerances meets the safety standards under the Food Quality Protection Act (FQPA). The safety finding determination of "reasonable certainty of no harm" is found in detail in each Reregistration Eligibility Decision (RED) and Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision (TRED) for the active ingredient. REDs and TREDs propose certain tolerance actions to be implemented to reflect current use patterns, to meet safety findings and change commodity names and groupings in accordance with new EPA policy. Printed copies of the REDs and TREDs 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/>. Electronic copies of REDs and TREDs are available on the internet at <http://www.epa.gov/pesticides/reregistration/status.htm>.

Additional information can be found in the Lindane RED and the Residue Chemistry Chapter document which supports the RED. A copy of the lindane Residue Chemistry Chapter is found in the Administrative Record and a hard copy is available in the public docket OPP-2002-0202, while an electronic copy is available through EPA's electronic public docket and comment system, EPA Dockets at <http://www.epa.gov/edocket/>. You may search for docket number OPP-2002-0202, then click on that docket number to view the Lindane RED support documents.

EPA is proposing to revoke certain specific existing tolerances for lindane because there are no longer any active registrations under FIFRA for uses on their associated commodities. It is EPA's general practice to propose revocation of those tolerances for residues of pesticide active ingredients on crop uses for which there are no active registrations under FIFRA, unless any person, in comments submitted on the proposal, indicates a need for the tolerance to cover residues in or on imported commodities or domestic commodities legally treated.

EPA published notices in the **Federal Register** under section 6(f)(1) of FIFRA announcing its receipt of requests from registrants to cancel or amend certain product registrations and delete certain lindane uses. Except for some seed treatment registrations, all other food use registrations for the insecticide lindane were canceled because EPA accepted the registrants' requests for voluntary cancellation.

In the **Federal Register** notice of September 30, 1998 (63 FR 52257) (FRL-6028-6), EPA announced the receipt of requests for amendments to delete specific uses, mushroom and nectarine, from certain lindane registrations. The Agency made the use deletions effective on March 29, 1999, and registrant sale and distribution of existing stocks was permitted for a period of 18 months; *i.e.*, until September 29, 2000. EPA believes that end users have had sufficient time, more than four years, to exhaust those existing stocks and for treated commodities to have cleared the channels of trade. Therefore, the Agency is proposing to revoke the associated tolerances in 40 CFR 180.133 for mushroom and nectarine to be effective on the date of publication of the final rule in the **Federal Register**.

In the **Federal Register** notice of January 27, 1999 (64 FR 4096) (FRL-6035-1), EPA announced the receipt of requests for amendments to delete specific uses, apricot, asparagus, avocado, eggplant, grape, guava, mango, pear, pecans, pepper, pineapple, quince, strawberry, and tomato, from certain lindane registrations. The Agency made the use deletions effective on July 26, 1999, and registrant sale and distribution of existing stocks was permitted for a period of 18 months; *i.e.*, until January 26, 2001. EPA believes that end users have had sufficient time, more than four years, to exhaust those existing stocks and for treated commodities to have cleared the channels of trade. Therefore, the Agency is proposing to revoke the associated tolerances in 40 CFR 180.133 for

apricot, asparagus, avocado, eggplant, grape, guava, mango, pear, pecans, pepper, pineapple, quince, strawberry, and tomato to be effective on the date of publication of the final rule in the **Federal Register**.

In the **Federal Register** notice of September 1, 1999 (64 FR 47786) (FRL-6098-9), EPA announced the receipt of requests to voluntarily cancel certain lindane registrations, two of which included plums among their effected commodity uses. The Agency made the registration cancellations effective on March 22, 2000, and registrant sale and distribution of existing stocks was permitted for one year after the cancellation requests were received by the Agency; *i.e.*, until June 9, 2000. EPA believes that end users have had sufficient time, more than four years, to exhaust those existing stocks and for treated commodities to have cleared the channels of trade. Therefore, the Agency is proposing to revoke the associated tolerances in 40 CFR 180.133 for plum; and plum, prune, fresh; to be effective on the date of publication of the final rule in the **Federal Register**.

In the **Federal Register** notice of November 3, 1999 (64 FR 59763) (FRL-6383-9), EPA announced the receipt of requests to voluntarily cancel certain lindane registrations, two of which included apples, cherries, and peaches among their effected commodity uses. The Agency made the registration cancellations effective on May 9, 2000, and registrant sale and distribution of existing stocks was permitted for one year after the cancellation requests were received by the Agency; *i.e.*, until August 18, 2000. EPA believes that end users have had sufficient time, more than four years, to exhaust those existing stocks and for treated commodities to have cleared the channels of trade. Therefore, the Agency is proposing to revoke the associated tolerances in 40 CFR 180.133 for apple, cherry, and peach to be effective on the date of publication of the final rule in the **Federal Register**.

In the **Federal Register** notice of August 28, 2002 (67 FR 55241) (FRL-7196-1), EPA announced the receipt of requests for amendments to delete specific uses, including spinach, from certain lindane registrations with an effective date of September 27, 2002. However, in a previous **Federal Register** notice of June 13, 2002 (67 FR 40730) (FRL-7178-4), EPA's receipt of requests for amendments to delete uses, including spinach, celery, collards, kale, kohlrabi, lettuce, mustard greens, and Swiss chard from a certain lindane technical registration was announced and made effective on December 10,

2002, and registrant sale and distribution of existing stocks was permitted for a period of 18 months; *i.e.*, until June 10, 2004. Here, EPA is proposing to revoke the associated tolerances in 40 CFR 180.133 for celery, collards, kale, kohlrabi, lettuce, mustard greens, spinach, and Swiss chard with an expiration/revocation date of June 10, 2005. The Agency believes that end users will have sufficient time to exhaust existing stocks and for treated commodities to have cleared the channels of trade.

In the **Federal Register** notice of January 26, 2005 (70 FR 3704) (FRL-7698-2), EPA announced receipt of a request for an amendment to delete specific lindane uses from one registration, including seed treatment uses for broccoli, Brussels sprouts, cabbage, and cauliflower. The Agency made the use deletions effective on February 25, 2005. However, registrant sale and distribution of existing stocks was permitted for a period of 18 months after the October 26, 2004 approval of the revision; *i.e.*, until April 26, 2006. The Agency believes that end users will have sufficient time to exhaust existing stocks and for treated commodities to have cleared the channels of trade by April 26, 2007. Therefore, EPA is proposing to revoke the associated tolerances in 40 CFR 180.133 for broccoli, Brussels sprouts, cabbage, and cauliflower with an expiration/revocation date of April 26, 2007.

The **Federal Register** notice of August 15, 2002 (67 FR 53350) (FRL-7192-3) corrected the effective date found in the notice of July 17, 2002 (67 FR 46976) (FRL-7186-4), which announced EPA's receipt of requests for amendments to delete specific uses, including cucumbers, cantaloupe, watermelon, okra, onions, pumpkins, and squash, from certain lindane registrations. The Agency corrected the use deletions to be effective on August 17, 2002, and registrant sale and distribution of existing stocks was permitted for a period of 18 months; *i.e.*, until February 17, 2004. The Agency believes that end users will have sufficient time to exhaust existing stocks and for treated commodities to have cleared the channels of trade also by June 10, 2005. Therefore, EPA is proposing to revoke the associated tolerances in 40 CFR 180.133 for cucumber, melon, okra, onion (dry bulb), pumpkin, squash, and squash, summer with an expiration/revocation date of June 10, 2005.

There are lindane end-use active registrations for seed treatments on cereal grains which are eligible for reregistration, provided that mitigation measures specified in the lindane RED

are implemented and the Agency can establish tolerances for the seed treatment uses of lindane. The establishment of seed treatment tolerances is conditioned on EPA's ability to make a determination that establishing the new tolerances meets the safety standard in FFDCA.

Currently, it is possible that livestock feed may be derived from grain grown from lindane-treated seed and residues of lindane in livestock would be expected. Consequently, the Agency believes that the existing livestock fat tolerances for lindane *per se* must be maintained until and unless the grain seed treatment uses are no longer registered. If the Agency is unable to make a safety finding that would support the establishment of tolerances on wheat, barley, oats, rye, corn, and sorghum for lindane residues resulting from seed treatment only, it will take steps to cancel the grain seed treatment registrations and propose revocation of the livestock fat tolerances. The Agency intends to complete its assessment of the seed treatment uses on or prior to August 3, 2006.

Because some tolerances will remain codified in 40 CFR 180.133 with expiration/revocation dates, EPA is proposing to amend the residue definition for lindane in order to harmonize with the International Union of Pure and Applied Chemistry nomenclature. Currently the tolerances are established in 40 CFR 180.133 and expressed in terms of residues of lindane *per se* (gamma isomer of benzene hexachloride). EPA is proposing to amend the lindane nomenclature to gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane.

B. What Is the Agency's Authority for Taking This Action?

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities (RACs), and processed foods. Section 408 of FFDCA, 21 U.S.C. 301 *et seq.*, as amended by the FQPA of 1996, Public Law 104-170, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on RACs, and processed foods (21 U.S.C. 346(a)). Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore "adulterated" under section 402(a) of the FFDCA. Such food may not be distributed in interstate commerce (21 U.S.C. 331(a) and 342(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.

EPA is proposing these tolerance actions to implement the tolerance recommendations made during the RED and TRED processes, and as follow-up on canceled uses of pesticides. As part of the RED and TRED processes, EPA is required to determine whether each of the amended tolerances meets the safety standards under the FQPA. The safety finding determination is found in detail in each Post-FQPA RED and TRED for the active ingredient. REDs and TREDs propose certain tolerance actions to be implemented to reflect current use patterns, to meet safety findings, and change commodity names and groupings in accordance with new EPA policy. Printed and electronic copies of the REDs and TREDs are available as provided in Unit II.A.

EPA has issued a Post-FQPA RED for lindane. REDs and TREDs contain the Agency's evaluation of the data base for these pesticides, including requirements for additional data on the active ingredients to confirm the potential human health and environmental risk assessments associated with current product uses, and the Agency's decisions and conditions under which these uses and products will be eligible for reregistration. In addition, REDs and TREDs recommend the establishment, modification, and/or revocation of specific tolerances. RED and TRED recommendations such as establishing or modifying tolerances, require assessment under the FQPA standard of "reasonable certainty of no harm," and are proposed in those documents under that standard. However, tolerance revocations recommended in REDs and TREDs may be proposed in this document without such assessment when the tolerances are no longer necessary.

EPA's general practice is to propose revocation of 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.

Furthermore, as a general matter, the Agency believes that retention of import tolerances not needed to cover any imported food may result in unnecessary restriction on trade of pesticides and foods. Under section 408 of the FFDCA, a tolerance may only be established or maintained if EPA determines that the tolerance is safe based on a number of factors, including an assessment of the aggregate exposure to the pesticide and an assessment of the cumulative effects of such pesticide and other substances that have a common mechanism of toxicity. In doing so, EPA must consider potential contributions to such exposure from all tolerances. If the cumulative risk is such that the tolerances in aggregate are not safe, then every one of these tolerances is potentially vulnerable to revocation. Furthermore, if unneeded tolerances are included in the aggregate and cumulative risk assessments, the estimated exposure to the pesticide would be inflated. Consequently, it may be more difficult for others to obtain needed tolerances or to register needed new uses. To avoid potential trade restrictions, the Agency is proposing to revoke tolerances for residues on crops uses for which FIFRA registrations no longer exist, unless someone expresses a need for such tolerances. Through this proposed rule, the Agency is inviting individuals who need these import tolerances to identify themselves and the tolerances that are needed to cover imported commodities.

Parties interested in retention of the tolerances should be aware that additional data may be needed to support retention. These parties should be aware that, 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 tolerances provide the necessary information. If the requisite information is not submitted, EPA may issue an order revoking the tolerance at issue.

C. When Do These Actions Become Effective?

With the exception of certain tolerances for which EPA is proposing specific expiration/revocation dates, the Agency is proposing that revocation of other tolerances become effective on the date of publication of the final rule in the **Federal Register** because their associated uses have been canceled, in

some cases, for several years. The Agency believes that existing stocks of pesticide products labeled for the uses associated with these other tolerances, proposed for revocation at the time of the final rule, have been completely exhausted and that treated commodities have had sufficient time for passage through the channels of trade. However, if EPA is presented with information that existing stocks would still be available and that information is verified, the Agency will consider extending the expiration date of the tolerance. If you have comments regarding existing stocks and whether the effective date allows sufficient time for treated commodities to clear the channels of trade, please submit comments as described under **SUPPLEMENTARY INFORMATION**.

Any commodities listed in this proposal treated with the pesticides subject to this proposal, and in the channels of trade following the tolerance revocations, shall be subject to FFDCA section 408(1)(5), as established by 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 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.

III. Are the Proposed Actions Consistent With International Obligations?

The tolerance revocations in this proposal are not discriminatory and are designed to ensure that both domestically-produced and imported foods meet the food safety standards established by the FFDCA. The same food safety standards apply to domestically produced and imported foods.

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. It is EPA's policy to harmonize U.S. tolerances with Codex MRLs to the extent possible, provided that the MRLs achieve the level of protection required under FFDCA. EPA's effort to harmonize with Codex MRLs is summarized in the tolerance reassessment section of individual Reregistration Eligibility Decision documents. 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, Regulations, and Dockets," 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. Statutory and Executive Order Reviews

In this proposed rule, EPA is proposing to revoke specific tolerances established under FFDCA section 408. The Office of Management and Budget (OMB) has exempted this type of action (*i.e.*, 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 proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed 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 proposed 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 104-113, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether revocations of tolerances might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. This analysis was published on December 17, 1997 (62 FR 66020), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this rule, the Agency hereby certifies that this proposed action 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 pesticide named in this proposed rule, the Agency knows of no extraordinary circumstances that exist as to the present proposal that would change the EPA's previous analysis. Any comments about the Agency's determination should be submitted to the EPA along with comments on the proposal, and will be addressed prior to issuing a final rule. 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 proposed 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 proposed 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 proposed 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 proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: April 1, 2005.

James Jones,
Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.133 in paragraph (a) is revised to read as follows:

§ 180.133 Lindane; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide lindane (gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane) in or on raw agriculture commodities as follows:

Commodity	Parts per million	Expiration/Revocation Date
Broccoli	1.0	4/26/07
Brussels sprouts	1.0	4/26/07
Cabbage	1.0	4/26/07
Cattle, fat	7.0	None
Cauliflower	1.0	4/26/07
Celery	1.0	6/10/05
Collards	1.0	6/10/05
Cucumber	3.0	6/10/05
Goat, fat	7.0	None
Hog, fat	4.0	None
Horse, fat	7.0	None
Kale	1.0	6/10/05
Kohlrabi	1.0	6/10/05
Lettuce	3.0	6/10/05
Melon	3.0	6/10/05
Mustard greens	1.0	6/10/05
Okra	1.0	6/10/05
Onion, dry bulb	1.0	6/10/05
Pumpkin	3.0	6/10/05
Sheep, fat	7.0	None
Spinach	1.0	6/10/05
Squash	3.0	6/10/05
Squash, summer	3.0	6/10/05
Swiss chard	1.0	6/10/05

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