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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0088; FRL-7358-6]

Bitertanol, Chlorpropham, Cloprop, Combustion Product Gas, Cyanazine, et al.; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document revokes certain tolerances and tolerance exemptions for residues of the insecticides combustion product gas, ethion, formetanate hydrochloride, nicotine-containing compounds, polyoxyethylene, and tartar emetic; herbicides chlorpropham, cyanazine, and tridiphane; fungicides 1,1,1-trichloroethane and triforine; and the plant regulators cloprop and 4,6-dinitro-o-cresol because these specific tolerances are either no longer needed or are associated with food uses that are no longer current or registered in the United States. Also, EPA is modifying certain ethion tolerances before they expire. Due to comment, EPA is not revoking specific tolerances for the fungicide bitertanol or the fungicide-insecticide dinocap at this time. The regulatory actions in this document contribute toward the Agency's tolerance reassessment requirements of the Federal Food, Drug, and Cosmetic Act (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 58 tolerances and tolerance exemptions. Because one tolerance was previously reassessed, 57 tolerances/exemptions are counted as reassessed toward the August 2006 review deadline.

DATES: This regulation is effective October 21, 2004; however, certain regulatory actions will not occur until the date specified in the regulatory text. Objections and requests for hearings must be received on or before September 21, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in

Unit IV. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket ID number OPP-2004-0088. 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., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hardcopy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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., ranchers and 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 December 10, 2003 (68 FR 68806) (FRL-7330-8), EPA issued a proposed rule to revoke certain tolerances and tolerance exemptions for residues of the fungicide and insecticide dinocap; insecticides combustion product gas, ethion, formetanate hydrochloride, nicotine-containing compounds, polyoxyethylene, and tartar emetic; herbicides chlorpropham, cyanazine, and tridiphane; fungicides bitertanol, 1,1,1-trichloroethane, and triforine; and the plant regulators cloprop and 4,6-dinitro-o-cresol. Also, the December 10 2003 proposal provided a 60-day comment period which invited public comment for consideration and for support of tolerance retention under the FFDCA standards.

This final rule revokes certain tolerances and tolerance exemptions for residues of insecticides combustion product gas, ethion, formetanate hydrochloride, nicotine-containing compounds, polyoxyethylene, and tartar emetic; herbicides chlorpropham, cyanazine, and tridiphane; fungicides 1,1,1-trichloroethane and triforine; and the plant regulators cloprop and 4,6-dinitro-o-cresol because these specific tolerances and exemptions correspond to uses no longer current or registered under FIFRA in the United States. The tolerances revoked by this final rule are no longer necessary to cover residues of the relevant pesticides in or on domestically treated commodities or commodities treated outside but imported into the United States. It is EPA's general practice to revoke those tolerances and tolerance exemptions for residues of pesticide active ingredients

on crop uses for which there are no active registrations under FIFRA, unless any person in comments on the proposal indicates a need for the tolerance or tolerance exemption to cover residues in or on imported commodities or domestic commodities legally treated.

Concerning the Reregistration Eligibility Decisions (REDs) for chlorpropham and ethion and the Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision (TRED) for chlorpropham mentioned in this rule, 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 number: 1-800-490-9198; fax number: 1-513-489-8695; Internet address: <http://www.epa.gov/ncepihom/>, and from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161; telephone number: 1-800-553-6847 or 703-605-6000; Internet address: <http://www.ntis.gov/>. Electronic copies of REDs and TREDs are available on the internet at <http://www.epa.gov/pesticides/reregistration/status.htm>.

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

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

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

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

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

This final rule does not revoke those tolerances for which EPA received comments stating a need for the tolerance to be retained. In response to the proposal published in the **Federal Register** of December 10, 2003 (68 FR

68806), EPA received comments as follows:

Comments. A private citizen from New Jersey expressed concern with pesticide use in general and the public's exposure in their daily lives. On December 10, 2003, the individual stated that there should be zero tolerance for all the chemicals mentioned in 40 CFR part 180.

Agency response. The private citizen's comment did not take issue with the Agency's conclusion that certain tolerances which were no longer needed should be revoked. It is EPA's general practice to propose revocation of tolerances for residues of pesticide active ingredients on crop uses for which FIFRA registrations no longer exist. 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.

1. *Bitertanol.* EPA received a comment from Bayer CropScience, who requested on January 15, 2004, that EPA not revoke the tolerance for bitertanol on bananas. Bayer acknowledged that while some previously submitted data may not meet current guideline requirements, it would support the tolerance on banana for import purposes with data.

Agency response. Because in a comment to the proposed rule, Bayer CropScience expressed a need for the retention of the banana tolerance for import purposes and intent to support the tolerance with data, EPA will not revoke the tolerance in 40 CFR 180.457 for residues of beta-([1,1'-biphenyl]-4-ylxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol, also called bitertanol, in or on banana (whole) at this time. EPA published a guidance on pesticide import tolerances and residue data for imported food in the **Federal Register** of June 1, 2000 (65 FR 35069) (FRL-6559-3). When the submitted data have been reviewed, EPA will re-evaluate that tolerance under FFDCA. If data adequate to support a safety finding are lacking, EPA intends to revoke the tolerance on banana in 40 CFR 180.457.

2. *Cloprop.* EPA received a comment from the Pineapple Growers Association of Hawaii (PGAH) who requested on January 9, 2004, and again on January 23, 2004, that the tolerance for the use of cloprop on pineapples not be revoked for 3 years in order to allow for the exhaustion of existing stocks of cloprop.

Agency response. On September 21, 2001, EPA amended its authorization of a specific emergency exemption under section 18 of FIFRA for application of cloprop on pineapple in Hawaii until

August 2, 2002. There are no active registrations for use of cloprop on pineapples and therefore, the pineapple tolerance is no longer needed. However, due to PGAH's comment on existing stocks, EPA is changing the revocation date of the tolerance in 40 CFR 180.325 for residues of 2-(m-chlorophenoxy) propionic acid, called cloprop, from application of the acid or of 2-(m-chlorophenoxy) propionamide in or on pineapple to February 1, 2007, which EPA believes allows sufficient time for existing stocks to be used and cloprop-treated pineapples to clear the channels of trade.

3. *Dinocap.* EPA received a comment from Dow AgroSciences, who requested on February 2, 2004, that EPA not revoke the tolerances for dinocap on apple and grape because it would support the tolerances on apple and grape for import purposes. Also, Dow AgroSciences noted that it had previously indicated such an intention which EPA included in a notice regarding the availability of the RED for dinocap published in the **Federal Register** of September 17, 2003 (68 FR 54449) (FRL-7321-8). In addition, Dow AgroSciences stated it would work with EPA to achieve compliance with the Agency's guidance on import tolerances and its data requirements.

Agency response. Because in a comment to the proposed rule, Dow AgroSciences expressed a need for the retention of the apple and grape tolerances for import purposes and intent to support the tolerances with data, EPA will not revoke the tolerances in 40 CFR 180.341 for combined residues that is a mixture of 2,4-dinitro-6-octylphenyl crotonate and 2,6-dinitro-4-octylphenyl crotonate, called dinocap, in or on apple and grape at this time. EPA published a guidance on pesticide import tolerances and residue data for imported food in the **Federal Register** of June 1, 2000 (65 FR 35069). When the submitted data have been reviewed, EPA will re-evaluate the tolerances under FFDCA. If data adequate to support a safety finding are lacking, EPA intends to revoke the tolerances on apple and grape in 40 CFR 180.341. In this final rule, the Agency will revise the text for tolerances in 40 CFR 180.341 paragraph (a) into tabular form.

No comments were received by the Agency concerning the following.

4. *Chlorpropham.* In the 1996 RED for chlorpropham, EPA required environmental fate and ecological effects data to maintain the spinach registration, which was registered as a Special Local Need under FIFRA 24(c) and was not being supported by the primary registrants of technical

chlorpropham. In February 2002, EPA canceled the last Special Local Need registration, but allowed use until December 31, 2002. On July 19, 2002, EPA reassessed the spinach tolerance in a TRED for chlorpropham. That reassessment decision was a recommendation to revoke the spinach tolerance because there are no active registrations and therefore, the tolerance is no longer needed. The Agency believes that there has been sufficient time for chlorpropham-treated spinach to clear the channels of trade. Therefore, EPA is revoking the interim tolerance in 40 CFR 180.319 regarding isopropyl m-chlorocarbanilate (CIPC), called chlorpropham, for residues in or on spinach.

5. *Combustion product gas.* EPA is revoking the tolerance exemption in 40 CFR 180.1051 for residues of the gas produced by the controlled combustion in air of butane, propane, or natural gas in or on all food commodities (except fresh meat) when used after harvest in modified atmospheres for stored product with prescribed conditions. The Agency is revoking the tolerance exemption because no active U.S. registrations have existed since 1993 and therefore, the tolerance exemption is no longer needed.

6. *Cyanazine.* In November 1994, EPA initiated a Special Review of cyanazine based on concerns that cyanazine may pose a risk of inducing cancer in humans from dietary, occupational, and residential exposure. In the **Federal Register** of July 25, 1996 (61 FR 39023) (FRL-5385-7), EPA announced a final determination to terminate the cyanazine Special Review. In the same notice, EPA accepted requests for the voluntary cancellation of cyanazine registrations effective December 31, 1999, and ordered the cancellations to take effect on January 1 2000, authorized sale and distribution of such products in the channels of trade in accordance with their labels through September 30, 2002, and prohibited the use of cyanazine products after December 31, 2002. EPA issued an order confirming the cyanazine cancellation on January 6, 2000 (65 FR 771) (FRL-6486-7).

EPA proposed to revoke the tolerances for cyanazine on April 23, 1999 (64 FR 19961) (FRL-6076-4). Only one significant comment was received in response to that document. Griffin L.L.C. requested that EPA not revoke the tolerances for cyanazine and due to Griffin's interest in maintaining those tolerances as import tolerances, the Agency did not take action on cyanazine at that time (July 21, 1999, 64 FR 39078) (FRL-6093-9). However, in a letter to

the Agency dated August 24, 1999, Griffin L.L.C. stated that it no longer needs EPA to maintain import tolerances for cyanazine. The Agency believes that there has been sufficient time for cyanazine-treated commodities to clear the channels of trade. Therefore, EPA is revoking the tolerances in 40 CFR 180.307 for residues of the herbicide 2-[[4-chloro-6-(ethylamino)-s-triazin-2-yl]amino]-2-methylpropionitrile, called cyanazine, in or on corn, forage; corn, fresh, kernel plus cob with husks removed; corn, grain; corn, stover; cotton, undelinted seed; sorghum, forage; sorghum, grain; sorghum, grain, stover; wheat, forage; wheat, grain; and wheat, straw.

7. *4,6-Dinitro-o-cresol.* EPA is revoking the tolerance in 40 CFR 180.344 for residues 4,6-dinitro-o-cresol (DNOC) and its sodium salt in or on apple from application to apple trees at the blossom stage because no active U.S. registrations have existed for its associated commodity use since 1993 and therefore, the tolerance is no longer needed.

8. *Ethion.* On July 31, 2002 (67 FR 49606) (FRL-7191-4), EPA published a final rule in the **Federal Register** which revoked ethion tolerances on citrus fruit, dried citrus pulp, and certain animal commodities with expiration/revocation dates of October 1, 2008. The Agency acknowledged that citrus and animal feed (citrus, dried pulp) with legal residues of ethion can take several years to clear channels of trade from ethion's last legal use date of December 31, 2004.

In the July 2002 final rule, EPA did not act on the cattle and milk fat tolerances for ethion because of an existing cattle ear tag product. On October 16, 2002 (67 FR 63909) (FRL-7276-6), EPA published a notice in the **Federal Register** under section 6(f)(1) of FIFRA announcing its receipt of a request from the registrant for cancellation of the last cattle ear tag product for ethion. EPA approved the registrant's request for voluntary cancellation and on June 4 2003, issued a cancellation order with an effective date of May 31, 2003, i.e., the order allowed the basic registrant to distribute and sell existing stocks of the canceled product until May 31, 2003. Therefore, EPA is revoking tolerances in 40 CFR 180.173 for residues of the insecticide ethion (O,O,O',O'-tetraethyl S,S'-methylene bisphosphorodithioate) including its oxygen analog (S-[[[(diethoxyphosphinothioyl) thio]methyl] O,O-diethyl phosphorothioate) in or on cattle, fat; cattle, meat byproducts; cattle, meat (fat basis); and milk fat (reflecting (n)

residues in milk), each with an expiration/revocation date of October 1, 2008. These dates are consistent with the expiration/revocation date concerning the ethion tolerance on dried citrus pulp, an animal feed. In addition and in accordance with the 2001 Registration Eligibility Decision (RED) for ethion, EPA is not only revoking the cattle tolerances, but also decreasing them based on an available ruminant feeding study to 0.2 parts per million (ppm) during the period before they expire on October 1, 2008. In the RED, EPA found that these revised tolerances are safe in accordance with section 408 of the FFDCA. A copy of the ethion RED is available at <http://www.epa.gov/edocket/> by searching for docket ID number OPP-2003-0265 concerning the proposed rule of (December 10, 2003, 68 FR 68806) (FRL-7330-8). The ethion RED is also available at <http://www.epa.gov/pesticides/reregistration/status.htm/>. See the ethion RED Part IV(C)(1)(b): Tolerance Summary.

Also, in the 2001 RED for ethion, EPA recommended that the citrus tolerances should be revoked, but also be raised during the period before they expire (from 10.0 to 25.0 ppm for dehydrated pulp and from 2.0 to 5.0 ppm for citrus fruits) based on the available citrus field trial and processing data. In the RED, EPA found that these revised tolerances are safe in accordance with section 408 of the FFDCA. (See the ethion RED Part IV(C)(1)(b): Tolerance Summary). Therefore, in 40 CFR 180.173, while the citrus, dried pulp and fruit, citrus tolerances will continue to expire on October 1, 2008, the Agency is increasing the tolerances for citrus, dried pulp (10 ppm) and fruit, citrus (2.0 ppm) during the period before they expire to 25.0 and 5.0 ppm, respectively.

In addition, to conform to current Agency practice, EPA is revising the commodity terminologies in 40 CFR 180.173 for "fruit, citrus" to "fruit, citrus, group 10"; and "milk fat (reflecting (n) residues in milk)" to "milk, fat, reflecting negligible residues in milk."

9. *Formetanate hydrochloride.* EPA had initiated negotiations with the registrant for formetanate hydrochloride due to Agency concerns. As one measure to reduce concerns, the registrant agreed to delete the product use on plums and prunes, which appear to benefit little from use of the product. Pursuant to section 6(f) of FIFRA, EPA received the request for voluntary amendments to delete the aforementioned uses from the registrations. On February 8, 2000, a

6(f)(1) notice of receipt of the request by the registrant was published in the **Federal Register** (65 FR 6208) (FRL-6489-6). EPA granted the registrant's request to waive the 180-day comment period, but the Agency provided a 30-day public comment period, and granted the requested amendments to delete those uses from registration labels on May 31, 2000. Except for the purpose of relabeling, the Agency had prohibited sale and distribution by the registrant after December 1, 1999, and by persons other than the registrant, including existing stocks, after June 1, 2000, of products labeled for use on plums and prunes.

Because there are no active registrations for use of formetanate hydrochloride on plums and prunes, the tolerances are no longer needed. Therefore, EPA is revoking the tolerances in 40 CFR 180.276(a)(1) for residues of the insecticide formetanate hydrochloride in or on plum, prune, fresh and in 40 CFR 180.276(a)(2) for residues of the insecticide formetanate hydrochloride in or on dried prunes.

10. *Nicotine-containing compounds.* On December 6, 2002 (67 FR 72673) (FRL-7281-5), EPA published a notice in the **Federal Register** under section 6(f)(1) of FIFRA announcing its receipt of a request from the registrant to amend a registration for a product whose active ingredient is a nicotine-containing compound and delete greenhouse food crops uses, including cucumber, lettuce, and tomato. (These were the last active food use registrations for nicotine-containing compounds). EPA approved the registrants' requests for voluntary deletion of these uses and allowed a period of 18 months for the registrant to sell and distribute existing stocks until December 4, 2004. The Agency believes that there is sufficient time for end users to exhaust those existing stocks and treated commodities to clear the channels of trade by December 4, 2005. Therefore, EPA is revoking the tolerances in 40 CFR 180.167 for residues of nicotine-containing compounds in or on cucumber, lettuce, and tomato with expiration/revocation dates of December 4, 2005.

11. *Polyoxyethylene.* EPA is revoking the tolerance exemptions in 40 CFR 180.1078 for residues of poly(oxy-1,2-ethanediyl), alpha-isooctadyl-omega-hydroxy, also called polyoxyethylene, in or on fish, shellfish, irrigated crops, meat, milk, poultry, and eggs because no active U.S. registrations have existed since 1990 and therefore, the tolerance exemptions are no longer needed.

12. *Tartar emetic.* EPA is revoking the tolerances in 40 CFR 180.179 for residues, calculated as combined

antimony trioxide, in or on fruit, citrus; grape, and onion because no active U.S. registrations have existed for their associated commodity uses since 1992.

13. *1,1,1-Trichloroethane.* EPA is revoking the tolerance exemption in 40 CFR 180.1012 for residues of 1,1,1-trichloroethane when used in the postharvest fumigation of citrus fruits because no active U.S. registrations have existed since 1989 and therefore, the tolerance exemption is no longer needed.

14. *Tridiphane.* On September 26, 2001 (66 FR 49184) (FRL-6802-1), EPA published a notice in the **Federal Register** under section 6(f)(1) of FIFRA announcing its receipt of a request from the registrant for cancellation of the last active tridiphane product registration. EPA approved the registrants' request for voluntary cancellation and issued a cancellation order with an effective date of April 5, 2002, which allowed the registrant to sell and distribute existing stocks of the canceled product until July 17, 2002. The Agency believes that there has been sufficient time for end users to exhaust those existing stocks and for treated commodities to clear the channels of trade. Therefore, EPA is revoking the tolerances in 40 CFR 180.424 for residues of 2-(3,5-dichlorophenyl)-2-(2,2,2-trichloroethyl)-oxirane, called tridiphane, in or on corn, grain, field; corn, forage; and corn, stover.

15. *Triforine.* On December 24, 1997 (62 FR 67365) (FRL-5761-8), EPA published a notice in the **Federal Register** under section 6(f)(1) of FIFRA announcing its receipt of a request from the registrant to amend a triforine product registration and delete certain triforine uses, including almonds, apples, apricots, asparagus, blueberries, cherries, cranberries, nectarines, plums, and prunes. EPA approved the registrants' requests for voluntary deletion of these uses and allowed a period of 18 months for the registrant to sell and distribute existing stocks (until approximately the end of 1999). Also, on July 31, 1998 (63 FR 41145) (FRL-6015-8), EPA published a notice in the **Federal Register** which announced cancellation of a triforine registration for non-payment of 1998 maintenance fee and issuance of a cancellation order which permitted the registrant to sell and distribute existing stocks of the canceled product until January 15, 1999.

The Agency believes that end users had sufficient time to exhaust those existing stocks and for treated commodities to have cleared the channels of trade. Therefore, EPA is revoking the tolerances in 40 CFR 180.382(a) for residues of triforine in or

on almond, hulls; almond; apple; apricot; bell pepper; blueberry; cantaloupe; cherry; cranberry; cucumber; eggplant; hop, dried cone; hop, spent; nectarine; peach; plum; prune, fresh; strawberry; and watermelon; and in 40 CFR 180.382(c) for residues of triforine in or on asparagus because no active U.S. registrations exist which cover those commodities and therefore, the tolerances are no longer needed.

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

It is EPA's general practice to propose revocation of tolerances for residues of pesticide active ingredients on crop uses for which FIFRA registrations no longer exist. 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?

With the exception of certain tolerances for cloprop, ethion, and nicotine-containing compounds for which EPA is revoking tolerances/exemptions with specific expiration/revocation dates, the Agency is modifying certain ethion tolerances before they expire and revoking tolerances/exemptions, and revising commodity terminologies effective on October 21, 2004. EPA is delaying the effectiveness of these modifications and revocations for 90 days following publication of this final rule to ensure that all affected parties receive notice of EPA's actions. For this final rule, tolerances that were revoked because registered uses did not exist concerned uses which have been canceled for more than a year. Therefore, commodities containing these pesticide residues should have cleared the channels of trade. EPA is revoking specific tolerances/exemptions with expiration/revocation dates of February 1, 2007 for cloprop, October 1, 2008 for ethion, and December 4, 2005 for nicotine-containing compounds.

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 residue of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of 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.

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 a 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 July 14, 2004, EPA has reassessed over 6,670 tolerances. In this final rule, EPA is revoking a total of 58 tolerances and tolerance exemptions, one of which was previously counted as reassessed (1 via the chlorpropham TRED). Therefore, 57 tolerances/exemptions are counted as reassessed toward the August 2006 review deadline of FFDCA section 408(q), as amended by FQPA in 1996.

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 Levels (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 (June 1, 2000, 65 FR 35069) (FRL-6559-3), 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-2004-0088 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 September 21, 2004.

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. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Clerk as described in Unit IV.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-2004-0088, 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

This final rule modifies and revokes specific tolerances established under section 408 of FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions (i.e., modification of a tolerance and 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 104-113, 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 establishment of tolerances, exemptions from tolerances, raising of tolerance levels, expansion of exemptions, or 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. These analyses for tolerance establishments and modifications, and for tolerance revocations were published on May 4, 1981 (46 FR 24950) and December 17, 1997 (62 FR 66020), respectively, and were 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, I certify that this 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 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: July 8, 2004.

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 180.167 is amended by revising the table in paragraph (a) to read as follows:

§ 180.167 Nicotine-containing compounds; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
Cucumber	2.0	12/4/05
Lettuce	2.0	12/4/05
Tomato	2.0	12/4/05

* * * * *

■ 3. Section 180.173 is amended by revising the table in paragraph (a) to read as follows:

§ 180.173 Ethion; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
Cattle, fat	0.2	10/1/08
Cattle, meat (fat basis)	0.2	10/1/08
Cattle, meat by-products	0.2	10/1/08
Citrus, dried pulp	25.0	10/1/08
Fruit, citrus, group 10	5.0	10/1/08
Goat, fat	0.2	10/1/08
Goat, meat	0.2	10/1/08
Goat, meat by-products	0.2	10/1/08
Hog, fat	0.2	10/1/08
Hog, meat	0.2	10/1/08
Hog, meat by-products	0.2	10/1/08
Horse, fat	0.2	10/1/08
Horse, meat	0.2	10/1/08
Horse, meat by-products	0.2	10/1/08
Milk, fat, reflecting negligible residues in milk	0.5	10/1/08
Sheep, fat	0.2	10/1/08

Commodity	Parts per million	Expiration/Revocation Date
Sheep, meat	0.2	10/1/08
Sheep, meat by-products	0.2	10/1/08

* * * * *

§ 180.179 [Removed]

■ 4. Section 180.179 is removed.
 ■ 5. Section 180.276 is amended by revising paragraph (a) to read as follows:

§ 180.276 Formetanate hydrochloride; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide formetanate hydrochloride (m-[[[(dimethylamino)methylene]amino]phenyl methylcarbamate hydrochloride]) in or on raw agricultural commodities as follows:

Commodity	Parts per million
Apple	3.0
Grapefruit	4.0
Lemon	4.0
Lime	4.0
Nectarine	4.0
Orange, sweet	4.0
Peach	5.0
Pear	3.0
Tangerine	4.0

* * * * *

§ 180.307 [Removed]

■ 6. Section 180.307 is removed.

§ 180.319 [Amended]

■ 7. Section 180.319 is amended by removing from the table the first entry for Isopropyl m-chlorocarbanilate (CIPC) which is the entry for “spinach.”

■ 8. Section 180.325 is revised to read as follows:

§ 180.325 2-(m-Chlorophenoxy) propionic acid; tolerances for residues.

(a) *General.* A tolerance is established for negligible residues of the plant regulator 2-(m-chlorophenoxy) propionic acid from application of the acid or of 2-(m-chlorophenoxy)propionamide in or on the following raw agricultural commodity:

Commodity	Parts per million	Expiration/Revocation Date
Pineapple	0.3	2/1/07

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

■ 9. Section 180.341 is amended by revising paragraph (a) to read as follows:

§ 180.341 2,4-Dinitro-6-octylphenyl crotonate and 2,6-dinitro-4-octylphenyl crotonate; tolerances for residues.

(a) *General.* Tolerances are established for combined negligible residues of a fungicide and insecticide that is a mixture of 2,4-dinitro-6-octylphenyl crotonate and 2,6-dinitro-4-octylphenyl crotonate in or on raw agricultural commodities as follows:

Commodity	Parts per million
Apple ¹	0.1
Grape ¹	0.1

¹There are no U.S. registrations on apple and grape as of October 24, 2002.

* * * * *

§ 180.344, 180.382, 180.424, 180.1012, 180.1051, and 180.1078 [Removed]

■ 10. Sections 180.344, 180.382, 180.424, 180.1012, 180.1051, and 180.1078 are removed.

[FR Doc. 04-16718 Filed 7-22-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 146

[CMS-2152-F2]

RIN 0938-AL42

Amendment to the Interim Final Regulation for Mental Health Parity

AGENCY: Centers for Medicare & Medicaid Services (CMS), DHHS.

ACTION: Amendment to interim final regulation.

SUMMARY: This document contains an amendment to the interim final regulation that implements the Mental Health Parity Act (MHPA) to conform the sunset date of the regulation to the sunset date of the statute under legislation passed by the 108th Congress.

DATES: *Effective date:* The amendment to the regulation is effective August 23, 2004.

Applicability dates: Under the amendment, the requirements of the