



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0234; FRL-9969-97]

Alpha-cypermethrin; Proposed Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to amend existing tolerances for residues of alpha-cypermethrin in or on fruit, citrus, group 10-10 and hog fat under the Federal Food, Drug, and Cosmetic Act (FFDCA). This proposal sets an expiration date for the existing tolerances while establishing new lower tolerance levels that will cover the same commodities when the current tolerances expire. EPA is proposing these changes to correct an error in a previous rulemaking that established these tolerances at an unintended level.

DATES: Comments must be received on or before *[insert date 60 days after publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2010-0234, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or email. 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 preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. This Proposal

EPA, on its own initiative under FFDCA section 408(e), 21 U.S.C. 346a(e), is proposing to amend the existing tolerances for the insecticide alpha-cypermethrin to reduce the allowable levels of the pesticide in or on fruit, citrus, group 10-10 from 10 parts per million (ppm) to 0.35 ppm and in or on hog, fat from 1.0 ppm to 0.10 ppm. EPA is proposing this action in order to correct a typographical error that occurred in the final rule establishing these tolerances on February 1, 2013 (78 FR 7266) (FRL-9376-1). In support of the 2013 final rule, EPA had reviewed residue field trial data and determined that the appropriate tolerance levels for fruit, citrus, group 10-10 and for hog, fat were 0.35 ppm and 0.10 ppm, respectively. Unfortunately, the instructions to the **Federal Register** contained incorrect tolerance values for these commodities and the incorrect tolerance levels were finalized in that rule. To remedy that error, EPA is proposing to correct the tolerance levels.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all

anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with FFDCA section 408(b)(2), for tolerances for residues of alpha-cypermethrin.

Alpha-cypermethrin and zeta-cypermethrin are enriched isomers of the pyrethroid insecticide cypermethrin. Although cypermethrin, zeta-cypermethrin, and alpha-cypermethrin are separate active ingredients with different end-use products, they are included together in the hazard evaluation for the purpose of human health risk assessment. The toxicology database for the cypermethrins includes studies with cypermethrin and both of its enriched isomers, and is considered complete for the purpose of risk assessment. When considering alpha-cypermethrin, the EPA also considers potential exposures from the other registered cypermethrins (*i.e.*, cypermethrin and zeta-cypermethrin), since the three active ingredients are essentially the same active from the mammalian toxicity perspective.

In the final rule published in the **Federal Register** of February 1, 2013 (78 FR 7266) (FRL-9376-1), EPA established tolerances for residues of alpha-cypermethrin in multiple commodities. Since the publication of that final rule, the toxicity profile of alpha-cypermethrin (as described in that rule) has not changed, and there have been no revisions to the toxicological database for the cypermethrins since that rule. In addition, although new tolerances have been established

since that 2013 rule (tolerances for residues of alpha-cypermethrin in or on food commodities/feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments at 0.05 ppm December 1, 2014 (79 FR 73210) (FRL-9918-88); zeta-cypermethrin in or on alfalfa, forage at 15 ppm and alfalfa, hay at 30 ppm December 24, 2014 (79 FR 77391) (FRL-9920-23) and corn, field, forage at 9.0 ppm, corn, field, stover at 30 ppm, corn, pop, stover at 30 ppm July 30, 2015 (80 FR 45435) (FRL-9929-74), these new tolerances have not increased exposure warranting a new risk assessment since the rulemaking in February 2013. Because the risk assessments supporting the establishment of the February 2013 tolerances assessed the correct tolerances associated with fruit, citrus, group 10-10 (0.35 ppm) and hog fat (0.10 ppm) and found them to be adequate, that risk assessment continues to support this proposal. Therefore, EPA is relying on those risk assessments in order to support the corrected tolerances for alpha-cypermethrin in fruit, citrus, group 10-10 and hog fat. EPA did ensure that the percent crop treated information assessed in the 2010 risk assessment is still valid. The most recent Screening Level Usage Analysis (SLUA) dated September 29, 2016 updating PCT data shows that the 2010 estimates are actually overestimates. For a detailed discussion of the aggregate risk assessments and determination of safety, refer to the February 1, 2013 **Federal Register** final rule and its supporting documents, available at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2010-0234.

Based on the risk assessments and information described in this unit, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to alpha-cypermethrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate tolerance-enforcement methods are available in PAM Volume II for determining residues of cypermethrin, zeta-cypermethrin and alpha-cypermethrin in plant (Method I) and livestock (Method II) commodities. Both methods are gas chromatographic methods with electron-capture detection (GC/ECD), and have undergone successful Agency petition method validations (PMVs). Method I has a limit of detection (LOD) of 0.01 ppm, and Method II has LODs of 0.005 ppm in milk, and 0.01 ppm in livestock tissues. These methods are not stereospecific; thus no distinction is made between residues of cypermethrin (all eight stereoisomers), zeta-cypermethrin (enriched in four isomers) and alpha-cypermethrin (two isomers).

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCa section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are multiple Codex MRLs for alpha-cypermethrin, but all are in conjunction with MRLs for total cypermethrin isomers (no MRLs have been established solely for alpha-

cypermethrin). However, although the definitions of the isomers covered differ formally between U.S. tolerances and Codex MRLs, the definitions of coverage are effectively harmonized since the tolerance enforcement methods are not stereospecific, and thus do not distinguish between residues of cypermethrin, zeta-cypermethrin and alpha-cypermethrin. For enforcement purposes, the same moiety is being regulated.

There is a Codex MRL established for citrus fruits at 0.3 ppm and there is no Codex MRL for hog fat. Because the U.S. use patterns differ from those upon which the Codex MRLs are based, EPA is not proposing to harmonize the U.S. tolerance for citrus fruit.

C. International Trade Considerations

In this proposal, EPA is proposing to reduce the existing tolerances for commodities in crop group 10-10 from 10 ppm to 0.35 ppm and on hog, fat from 1.0 ppm to 0.1 ppm. The Agency intends to reduce these tolerances to correct the tolerance levels that EPA intended to establish in a previous rulemaking based on available residue data.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA will notify the WTO of its intent to revise this tolerance. In addition, the SPS Agreement requires that Members provide a "reasonable interval" between the publication of a regulation subject to the Agreement and its entry into force in order to allow time for producers in exporting Member countries to adapt to the new requirement. At this time, EPA is proposing to allow the existing tolerances remain for a period of six months after the effective date of the final rule, in order to address this requirement.

This reduction in tolerance levels is not discriminatory; the same food safety standard contained in the FFDCFA applies equally to domestically produced and imported foods.

V. Conclusion

Therefore, EPA is proposing to amend existing tolerances for residues of alpha-cypermethrin in or on fruit, citrus, group 10-10 and hog, fat at 0.35 ppm and 0.10 ppm, respectively. EPA is also proposing to establish a six-month expiration date for the existing tolerances while establishing new lower tolerances for these commodities.

VI. Statutory and Executive Order Reviews

This proposed action would amend existing tolerances under FFDCA section 408(e) in an action taken on the Agency's own initiative. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this proposed action has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), nor is it subject to Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" ((82 FR 9339, February 3, 2017). This proposed action 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 (UMRA) (2 U.S.C. 1501 *et seq.*). Nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This proposed 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 (NTTAA) (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 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 in the **Federal Register** of May 4, 1981 (46 FR 24950) and December 17, 1997 (62 FR 66020) (FRL-5753-1), respectively, and were provided to the Chief Counsel for Advocacy of the Small Business Administration. In a memorandum dated May 25, 2001, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation. Furthermore, for alpha-cypermethrin, the Agency knows of no extraordinary circumstances that exist as to the present rule that would change EPA's previous analysis. Taking into account this analysis, and available information concerning the pesticides listed in this rule, EPA hereby certifies that this rule will not have a significant negative economic impact on a substantial number of small entities. In addition, the Agency has determined that this proposed 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 action directly regulates growers, food processors, food handlers, and food retailers, not States. This proposed action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed action does not have any “tribal implications” as described in Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 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 action 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 action.

List of Subjects in 40 CFR Part 180

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

Dated: November 13, 2017.

Michael Goodis,
Director, Registration Division, 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 § 180.418, paragraph (a)(3):

a. Revise the existing entries for “Fruit, citrus, group 10-10”; and “Hog, fat”; and add footnote 1”; and

b. Add alphabetically the following entries for “Fruit, citrus, group 10-10”; and “Hog, fat”.

The additions and revisions read as follows:

§ 180.418 Cypermethrin and isomers alpha-cypermethrin and zeta-cypermethrin; tolerances for residues.

(a)(3) * * *

Commodity	Parts per million
* * *	* * *
Fruit, citrus, group 10-10 ¹	10
Fruit, citrus, group 10-10	0.35
* * *	* * *
Hog, fat ¹	1.0
Hog, fat	0.10
* * *	* * *

¹This tolerance expires on *[insert date of publication six months after the date of publication in the Federal Register]*.

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