



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0210; FRL-9920-23]

Zeta-cypermethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerances for residues of zeta-cypermethrin in or on alfalfa, forage and alfalfa, hay. FMC Corporation requested the amendment of the tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0210, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001.

The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, 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. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0210 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request,

identified by docket ID number EPA-HQ-OPP-2014-0210, 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 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>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 23, 2014 (79 FR 29729) (FRL-9910-29), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8214) by FMC Corporation, 1735 Market St., Philadelphia, PA 19103. The petition requested EPA to amend the tolerances in 40 CFR 180.418 for residues of the insecticide zeta-cypermethrin, *S*-cyano (3-phenoxyphenyl) methyl (\pm)(cis-trans 3-(2-2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate, in or on alfalfa, forage from 5.0 parts per million (ppm) to 15.0 ppm and alfalfa, hay from 15.0 ppm to 30.0 ppm. That document

referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Instead of the proposed tolerances in alfalfa hay at 30.0 ppm and alfalfa forage at 15.0 ppm, EPA is establishing these tolerances at 30 ppm and 15 ppm, respectively. The Agency establishes tolerances using whole numbers for tolerances of 10 ppm or more, per the Organization for Economic Cooperation and Development (OECD) User Guide ENV/JM/MONO(2011)2 for the OECD tolerance calculation procedure.

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), and the factors specified in 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 for zeta-cypermethrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with zeta-cypermethrin follows.

Zeta-cypermethrin is an enriched isomer of the pyrethroid insecticide cypermethrin. In addition, alpha-cypermethrin is also an enriched isomer of cypermethrin. Although cypermethrin, alpha-cypermethrin, and zeta-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.

The aggregate risk assessment for zeta-cypermethrin must consider potential exposure from all cypermethrins (i.e., cypermethrin, alpha-cypermethrin, and zeta-cypermethrin), since the three active ingredients are considered to be essentially the same from the mammalian toxicity perspective. The revised tolerances associated with the increased use rate on alfalfa forage and hay have no impact on the existing dietary exposure assessment for the cypermethrins. Alfalfa forage and hay are livestock feed items that are not directly entered into the dietary exposure assessment. In addition, the increased tolerances in the alfalfa forage and hay will not have an impact on the existing livestock commodity tolerances; these tolerances were established at levels determined largely due to the potential for residues in other commodities (such as clover and trefoil)

with higher tolerances and which also constitute a greater percentage of the estimated livestock diet for zeta-cypermethrin. Therefore, the proposed increased use rates on alfalfa grown for hay and forage will not result in the need to increase the tolerances in livestock commodities. Consequently, the previously conducted dietary exposure assessment will not be affected by the proposed increased use rate and corresponding tolerances for alfalfa hay and forage. Furthermore, the drinking water estimates used in the existing dietary exposure assessment are more protective (higher) than those recently estimated based on the proposed use pattern and using updated drinking water models.

In the final rule published in the **Federal Register** of December 7, 2012 (77 FR 72975) (FRL-9371-7), EPA established tolerances for residues of zeta-cypermethrin in multiple commodities. Since the publication of that final rule, the toxicity profile of zeta-cypermethrin has not changed and since the revised tolerances associated with the increased use rate on alfalfa forage and hay have no impact on the existing dietary and aggregate risk determinations, the risk assessments that supported the establishment of the zeta-cypermethrin tolerances published in the December 7, 2012 **Federal Register** final rule remain valid. Therefore, EPA is relying on those risk assessments in order to support the revised tolerances for zeta-cypermethrin in alfalfa forage and hay.

An updated aggregate risk assessment was not needed to support the proposed increased tolerances for residues in alfalfa forage and hay, since these are livestock feed items, and the increased tolerances will not result in a change in the previously estimated dietary (food and water) or residential exposure estimates for zeta-cypermethrin. For a detailed discussion of the aggregate risk assessments and determination of safety, please refer to the December 7, 2012 **Federal Register** final rule and its supporting documents,

available at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2010-0472. EPA is also relying on those supporting risk assessments and findings to support of this final rule.

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 zeta-cypermethrin residues. Further information can also be found in the document: “Zeta-Cypermethrin - Human Health Risk Assessment to Support Increased Tolerances and Use Rate on Alfalfa Hay and Forage” in docket ID number EPA-HQ-OPP-2014-0210.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate tolerance enforcement methods are available in Pesticide Analytical Manual (PAM) Volume II for determining residues of alpha-cypermethrin, cypermethrin, and zeta-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). These methods are not stereospecific; thus no distinction is made between residues of cypermethrin (all 8 stereoisomers), alpha-cypermethrin (enriched in 2 isomers), and zeta-cypermethrin (enriched in 4 isomers). The January 1994 Food and Drug Administration

(FDA) PESTDATA database (PAM Volume I) indicates that residues of cypermethrin are completely recovered (>80%) using multi-residue method sections 302 (Luke), 303 (Mills, Onley, and Gaither), and 304 (Mills fatty food).

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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Currently established U.S. tolerances for cypermethrin, alpha-cypermethrin, and zeta-cypermethrin are included in the same part in title 40 of the Code of Federal Regulations (CFR), but have separate sections and different crops listed. There are multiple Codex MRLs for zeta-cypermethrin, but all are in conjunction with MRLs for total cypermethrin isomers (no MRLs have been established solely for zeta-cypermethrin). However, although the definitions differ formally, they are effectively harmonized since the tolerance-enforcement methods are not stereospecific, and thus do

not distinguish between residues of cypermethrin, alpha-cypermethrin, and zeta-cypermethrin. For enforcement purposes, the same moiety is being regulated.

There is a Codex MRL established in alfalfa fodder at 30 ppm, which would be harmonized with the proposed tolerance in alfalfa hay. Codex has not established an MRL in alfalfa forage.

C. Response to Comments

One comment was received from the general public urging the Agency to tighten regulations for pesticides tolerances and uses. The commenter particularly addressed carcinogenic chemicals and their effects on children's health.

Cypermethrin is classified as a "Possible human carcinogen" based on the presence of benign tumors (lung adenomas) in an adequate mouse carcinogenicity study with cypermethrin. The presence of common benign tumors (lung adenomas), in one species (mice) and one sex (female), with no increase in the proportion of malignant tumors or decrease in the time-to-tumor occurrence, together with the lack of mutagenic activity, was not considered strong enough to warrant a linear or no-threshold approach to quantitation of human cancer risk. Quantification of risk using a non-linear approach (i.e., acute population adjusted dose (aPAD), acute reference dose (aRfD)) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to cypermethrin. The Agency is using the acute dietary endpoint because, due to the rapid reversibility of the most sensitive neurotoxicity endpoint used for quantifying risks, there is no increase in hazard with increasing dosing duration;

therefore, the acute dietary endpoint is protective of the endpoints from repeat dosing studies, including cancer dietary exposures.

No evidence of carcinogenicity was observed in carcinogenicity studies in rats with cypermethrin or in mice with alpha-cypermethrin. Carcinogenicity studies are not available for zeta-cypermethrin; however, based on the structural and toxicological similarities to alpha cypermethrin and cypermethrin the carcinogenic potential is expected to be similar. Therefore, the Agency considers conclusions regarding the carcinogenic potential of cypermethrin to be applicable to alpha-cypermethrin and zeta-cypermethrin.

The Agency has considered all the available data, including all available data concerning the potential for carcinogenicity and concluded after conducting a risk assessment, that there is a reasonable certainty that no harm will result from aggregate human exposure to zeta-cypermethrin. EPA gives special consideration to the potential susceptibility and exposures of infants and children to pesticide chemical residues and is confident that it has chosen endpoints, points of departure, and uncertainty factors that are protective for all populations, including infants and children, and that have a strong scientific foundation. In addition, there are ongoing efforts to develop data to gain more information concerning the potential sensitivity of infants and young children to pyrethroids as a class.

V. Conclusion

Therefore, tolerances are amended for residues of zeta-cypermethrin, *S*-cyano(3-phenoxyphenyl)methyl (\pm)(cis-trans3-(2-2-dichloroethenyl)-

2,2dimethylcyclopropanecarboxylate, including its metabolites and degradates in or on alfalfa, forage at 15 ppm and alfalfa, hay at 30 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this 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) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *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).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of

power and responsibilities established by Congress in the preemption provisions of FFDCa section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not 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.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: December 10, 2014.

G. Jeffrey Herndon,

Director, Registration Division, 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. In § 180.418, place the entries “Alfalfa, hay” and “Alfalfa, forage” in alphabetical order in the table in paragraph (a)(2) and revise them to read as follows:

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

(a) * * *

(2) * * *

Commodity	Parts per million
Alfalfa, forage	15
Alfalfa, hay	30
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[FR Doc. 2014-29788 Filed 12/23/2014 at 8:45 am; Publication Date: 12/24/2014]