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## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2008-0824; FRL-9966-10]**

**RIN 2070-ZA16**

### **Tebufenozide; Pesticide Tolerance Actions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is establishing tolerances for residues of tebufenozide in or on multiple commodities, which are identified and discussed later in this document. In addition, EPA is correcting commodity definitions, updating crop group tolerances, and harmonizing US tolerances with Codex. EPA is also removing tolerances for residues of tebufenozide that are no longer needed due to the changes listed. EPA is also amending the existing tolerance for almond, hulls under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert the date of publication in the **Federal Register***]. 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 [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-2008-0824, 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:** Christina Scheltema, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-2201; email address: [scheltema.christina@epa.gov](mailto:scheltema.christina@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 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](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-2008-0824 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-2008-0824, 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. Background**

### *A. What Actions is the Agency Taking?*

In the **Federal Register** of October 14, 2016 (81 FR 71029) (FRL-9952-75), EPA proposed, pursuant to its authority in section 408(e) of the FFDCA, 21 U.S.C. 346a(d)(3), to establish, amend, and remove certain tolerances for residues of tebufenozide. The Agency proposed that 40 CFR 180.482 be amended by establishing tolerances for residues of tebufenozide in or on the following commodities: bushberry subgroup 13-07B at 3.0 part per million (ppm); caneberry subgroup 13-07A at 3.0 ppm; fruit, citrus, group 10-10 at 2.0 ppm; fruit, pome group 11-10 at 1.0 ppm; nut, tree, group 14-12 at 0.1 ppm; sugarcane, cane at 1.0 ppm; sugarcane, molasses at 3.0 ppm; vegetable, fruiting, group 8-10 at 1.0 ppm. EPA also proposed to increase the existing tolerances for almond, hulls from 25 to 30 parts per million (ppm). Finally, EPA proposed to remove as unnecessary the following tolerances upon establishment of the new tolerances: apple; berry, group 13; fruit, citrus, group 10; fruit, pome; nut, tree, group 14; pistachio; vegetable, fruiting, group 8; and walnut.

The proposed rule of October 14, 2016 (FRL-9952-75), provided for a 60-day comment period and invited public comments. EPA received anonymous public comments from three private citizens. The comments and EPA's response are presented in Unit IV. E.

In this final rule, the Agency is establishing, modifying, and revoking the tolerances as indicated in its proposal of October 14, 2016, under its authority in FFDCA section 408(e)(1)(A). EPA is also establishing an expiration date for the existing tolerances for fruit, pome.

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

EPA may issue a regulation establishing, modifying, or revoking a tolerance under FFDCA section 408(e).

*C. When Do These Actions Become Effective?*

As stated in the **DATES** section, this regulation is effective [*insert the date of publication in the Federal Register*]. In addition, the tolerance for fruit, pome, at 1.5 ppm, expires on May 16, 2018.

**III. Determination of Safety.**

There have been no changes in the Agency's assessment of the safety of these tolerances since the issuance of the proposal, and no additional information or concerns were raised by the commenters warranting a reconsideration of the Agency's safety finding in the proposal. Therefore, the Agency is incorporating the Aggregate Risk Assessment and Determination of Safety as contained in Unit III. of its October 14, 2016 proposal and relying upon the findings therein to support its conclusion that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to tebufenozide residues.

**IV. Other Considerations.**

*A. Analytical Enforcement Methodology.*

An adequate enforcement methodology is available to enforce the tolerance expression, as indicated in the proposal.

*B. International Residue Limits.*

In making its tolerance decisions, EPA seeks to harmonize US tolerances with international standards whenever possible, consistent with US 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.

As indicated in the proposed rule, EPA is harmonizing its U.S. tolerances for sugarcane; fruit, citrus, group 10-10; fruit, pome, group 11-10; and almond, hulls, with Codex MRLs.

### *C. International Trade Considerations*

In this final rule, EPA is converting the existing crop group tolerance on fruit, pome, to fruit, pome, group 11-10, and in the process, reducing the crop group tolerance from 1.5 ppm to 1.0 ppm to harmonize with Codex MRLs. For the commodities included in crop group 11-10 that are not covered by the fruit, pome tolerance, the new tolerances allow import of those additional commodities with residues of tebufenozide up to 1.0 ppm, which is not currently permitted under the existing tolerance. However, for the commodities currently in the crop group that continue to be included in crop group 11-10, the tolerance is reduced from 1.5 ppm to 1.0 ppm. With very few exceptions, all of the

MRLs for tebufenozide on pome fruits are already at or below EPA's proposed tolerance level of 1.0 ppm. As a result, EPA believes that a reasonable interval between the publication of this rule and the effective date of these tolerances is not necessary; therefore, the Agency proposes to make the tolerance of 1.0 ppm for crop group 11-10, fruit, pome, effective upon publication of this final rule. Nonetheless, because this tolerance change represents a reduction in the allowable amount of tebufenozide residues allowed in or on fruit, pome, crop group 11, EPA is establishing an expiration date for the existing tolerances for fruit, pome, that is six months from the date of publication of this final rule. Before that date, residues of tebufenozide on those commodities will be permitted up to the 1.5 ppm level under the existing fruit, pome, tolerance; after that date, residues will need to comply with the new reduced 1 ppm tolerance level under crop group 11-10.

The Agency is reducing the tolerances on commodities in this crop group to harmonize with the Codex MRL. The reduction is appropriate based on available data and residues levels resulting from registered use patterns. 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. None of the other tolerance actions taken in this rulemaking restrict permissible pesticide residues below currently allowed levels in the United States. In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to promptly publish this action with the WTO.

#### *D. Existing Stocks Considerations*

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 FFDCFA section 408(1)(5), as established by FQPA. Under this unit, any residues of this pesticide 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.

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.

#### *E. Response to Comments*

The Agency received three comments on its October 14, 2016 proposal. The comments and EPA's responses follow.

*Comment by private citizen.* An anonymous commenter expressed concerns about the toxicity of tebufenozide and pesticides in general.

*Agency response.* The commenter did not take issue with EPA's specific proposal to establish or amend tolerances for tebufenozide or with the underlying risk assessments supporting the proposal. The commenter did not refer to any specific studies pertaining to the toxicity of tebufenozide or the conclusions of the tebufenozide risk assessments.

Therefore, EPA has not changed its previous determination that the tolerances in question are safe and is not making any changes in response to these comments.

*Comment by private citizen.* An anonymous commenter expressed support for implementing the tolerances in the proposed rule. However, the commenter also expressed some concern about the potential of tebufenozide to cause harm to humans, other mammals, and ecosystems.

*Agency response.* The commenter supported EPA's specific proposal to establish and amend tolerances with tebufenozide. Although the commenter expressed concern regarding the potential effects of tebufenozide, he or she did not refer to any specific studies pertaining to the conclusions of the risk assessments. Therefore, EPA has not changed its previous determination that the tolerances in question are safe.

*Comment by private citizen.* An anonymous commenter supported the crop group reassignments in the proposed rule. This commenter also expressed concern that the public might not support the proposed increase of the almond hull tolerance from 25 to 30 ppm.

*Agency Response:* This commenter did not provide any evidence to support his or her concern regarding public support for the proposed increase of the almond hull tolerance.

Therefore, the Agency has not changed its previous determination that the 30 ppm almond hull tolerance is safe.

## **V. Conclusion**

EPA has determined that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to tebufenozide residues. The details of the Agency's assessment of the safety of the tebufenozide tolerances may be found in the proposed rule; there have been no changes since its issuance. Therefore, EPA is incorporating the Aggregate Risk Assessment and Determination of Safety as contained in Unit III of its October 14, 2016 proposal to support the conclusion of a reasonable certainty of no harm.

The Agency hereby establishes tolerances for residues of tebufenozide in bushberry subgroup 13-07B at 3.0 ppm; caneberry subgroup 13-07A at 3.0 ppm; fruit, citrus, group 10-10 at 2.0 ppm; fruit, pome group 11-10 at 1.0 ppm; nut, tree, group 14-12, at 0.1 ppm; sugarcane, cane at 1.0 ppm; sugarcane, molasses at 3.0 ppm; and vegetable, fruiting, group 8-10 at 1.0 ppm. The Agency is also increasing the tolerance for almond, hulls from 25 ppm to 30 ppm. Further, upon the establishment of these tolerances, the Agency is removing the existing tolerances for apple; berry, group 13; fruit, citrus, group 10; nut, tree, group 14; pistachio; vegetable, fruiting, group 8; and walnut because they will be superseded by the newly established tolerances. Finally, the Agency is establishing a six-month expiration date for the current fruit, pome, tolerance.

## **VI. Statutory and Executive Order Reviews**

In this final rule, EPA is establishing, modifying, and revoking tolerances under FFDCA section 408(e). The Office of Management and Budget (OMB) has exempted these types of actions (e.g., establishment and 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, it 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). 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 (UMRA) (2 U.S.C. 1501 *et seq.*). 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 final rule 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 establishment 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 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. (This Agency document is available in the docket for this rule). Furthermore, for tebufenozide, 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. The Agency has determined that this rule 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 rule directly regulates growers, food processors, food handlers, and food retailers, not States. This

rule does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCFA section 408(n)(4). 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 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 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.

## **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: October 24, 2017.

Richard P. Keigwin, Jr.

*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. In § 180.482, the table in paragraph (a)(1) is revised to read as follows:

**§ 180.482 Tebufenozide; tolerances for residues.**

(a) \* \* \* (1) \* \* \*

Commodity	Parts per million
Almond, hulls	30
Apple, dry pomace	3.0
Apple, wet pomace	3.0
Bushberry subgroup 13-07B	3.0
Brassica, head and stem, subgroup 5A	5.0
Brassica, leafy greens, subgroup 5B	10.0
Canola, refined oil	4.0
Canola, seed	2.0
Caneberry subgroup 13-07A	3.0
Citrus, oil	15.0

Cotton	1.5
Cotton, gin byproducts	30
Cranberry	1.0
Fruit, citrus, group 10-10	2.0
Fruit, pome <sup>1</sup>	1.5
Fruit, pome, group 11-10	1.0
Grape	3.0
Kiwifruit <sup>2</sup>	0.5
Leaf petioles subgroup 4B	2.0
Leafy greens subgroup 4A	10.0
Nut, tree, group 14-12	0.1
Peppermint, tops	10.0
Spearmint, tops	10.0
Sugarcane, cane	1.0
Sugarcane, molasses	3.0
Turnip, greens	9.0
Turnip, roots	0.3
Vegetable, fruiting, group 8-10	1.0
Vegetable, tuberous and corm, except potato, subgroup 1D	0.015

<sup>1</sup> This tolerance expires on May 16, 2018.

<sup>2</sup> There are no U.S. registrations on kiwifruit.

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