



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0230; FRL-10018-73]

Ethaboxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of ethaboxam in or on beet, sugar, roots. Valent U.S.A. LLC., requested these 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-2019-0230, 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information

on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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 Publishing 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-2019-0230 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-2019-0230, 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 August 2, 2019 (84 FR 37818) (FRL-9996-78), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8747) by Valent U.S.A. LLC, P.O. Box 8025, Walnut Creek, CA 94596-8025. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide, ethaboxam, (N-(cyano-2-thienylmethyl)-4-ethyl-2-(ethylamino)-5-

thiazolecarboxamide), in or on beet, sugar, root at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by Valent U.S.A. LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA has modified the commodity definitions, tolerance levels, and tolerances being established. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the 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 the 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 ethaboxam including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with ethaboxam follows.

On August 8, 2017, EPA published in the *Federal Register* a final rule establishing tolerances for residues of ethaboxam in or on several commodities based on the Agency's conclusion that aggregate exposure to ethaboxam is safe for the general population, including

infants and children. See (82 FR 36086) (FRL-9961-69). EPA is incorporating the following portions of that document by reference here, as they have not changed in the Agency's current assessment of ethaboxam tolerances: the toxicological profile and points of departure; description of the assumptions for assessing exposure from residues in or on food, in drinking water, and residential exposures; cancer assessment and conclusion that a nonlinear reference dose (Rfd) approach is appropriate for assessing cancer risk; conclusions about cumulative risk; Agency's determination regarding the children's safety factor; and tolerance expression, which have not changed. EPA's risk assessment, titled "Ethaboxam. Human Health Risk Assessment for Non-food Seed Treatment," supports the tolerances established in March 9, 2012, and can be found at <http://www.regulations.gov> at docket ID EPA-HQ-OPP-2011-0908-0003. Although the Agency incorporated the assumptions for exposure assessment from the March 9, 2012, final rule and risk assessment, the Agency conducted a revised risk assessment to incorporate exposure to residues of ethaboxam from use as a seed treatment on sugar beets. The updated risk assessment, titled "Ethaboxam. Human Health Risk Assessment Supporting the Proposed New Use on Sugar Beet Seeds," is in docket ID number EPA-HQ-OPP-2019-0230.

EPA's exposure assessments have been updated to include the additional exposure from use of ethaboxam on sugar beet, relied on tolerance-level residues, an assumption of 100 percent crop treated (PCT), and 2018 default processing factors for all processed commodities, except for potato, grape, and sugar beet processed commodities, for which the processing studies demonstrated no concentration. EPA's aggregate exposure assessment incorporated this additional dietary exposure, which includes exposure through drinking water. However, drinking water exposures are not impacted by the new use on sugar beet, and thus have not changed since the last assessment. Additionally, although sugar beet molasses and dried pulp are considered significant livestock feed items, the requested new use on sugar beets will not result in the need to establish ethaboxam tolerances in livestock commodities.

An acute dietary risk assessment was not conducted since effects attributable to a single

exposure were not identified. Chronic dietary risks are below the Agency's level of concern: 36% of the chronic population adjusted dose (cPAD) for children 1 to 2 years old, the group with the highest exposure. Due to no existing registered or proposed residential uses associated with ethaboxam, there is not expected to be any residential handler exposure or post-application dermal exposures. Residential post-application oral and inhalation exposures are not expected. Since there are no residential uses, the aggregate exposure is equal to the dietary exposure and thus is not of concern.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to ethaboxam residues. More detailed information on the subject action to establish tolerances in or on beet, sugar, roots can be found in the document entitled, "Ethaboxam. Human Health Risk Assessment Supporting the Proposed New Use on Sugar Beet Seeds" by going to <http://www.regulations.gov>. The referenced document is available in the docket established by this action, which is described under ADDRESSES. Locate and click on the hyperlink for docket ID number EPA-HQ-OPP-2019-0230.

IV. Other Considerations

A. Analytical Enforcement Methodology

There are adequate residue analytical methods for enforcing tolerances for ethaboxam residues of concern in/on the registered plant commodities. The methods include high-performance liquid chromatography with tandem mass-spectrometric detection (LC-MS/MS) for determining residues in/on sugar beets.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

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 has not established MRLs for ethaboxam in or on beet, sugar, roots; however, Canada's Pest Management Regulatory Agency (PMRA) is simultaneously evaluating the proposed use for ethaboxam on sugar beet seeds. EPA is establishing the same tolerance level for beet, sugar, roots as PMRA's proposed MRL of 0.03 ppm. Therefore, there are no harmonization issues.

C. Revisions to Petitioned-For Tolerances

The requested tolerance in "beet, sugar, root" was modified to read "beet, sugar, roots" to be consistent with Agency naming practices. The petitioned-for tolerance level of 0.01 ppm in beet, sugar, roots has been modified to 0.03 ppm based on the per-trial average residue corrected for all field trial dissipation. This is consistent with the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedure when all residues are corrected for apparent storage stability decline.

V. Conclusion

Therefore, tolerances are established for residues of ethaboxam in or on beet, sugar, roots at 0.03 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance 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), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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: January 15, 2021.

Marietta Echeverria

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

2. In § 180.622, amend paragraph (a) by designating the table and adding in alphabetical order in newly designated table 1 to paragraph (a) an entry for “Beet, sugar, roots” to read as follows:

§ 180.622 Ethaboxam; tolerances for residues.

* * * * *

Table 1 to Paragraph (a)

Commodity	Parts per million							
* * *	*	*	*	*	*	*	*	*
Beet, sugar, roots	0.03							
* * *	*	*	*	*	*	*	*	*

* * * * *