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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.

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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 February 9, 2021. Objections and

requests for hearings must be received on or before April 12, 2021, 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](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,

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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](mailto: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

April 12, 2021. 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](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](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

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``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](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 proceeded

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](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](mailto: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

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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

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

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

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2. In Sec. 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:

Sec. 180.622 Ethaboxam; tolerances for residues.

\* \* \* \* \*

Table 1 to Paragraph (a)

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Parts per

Commodity million

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\* \* \* \* \*

Beet, sugar, roots......................................... 0.03

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[FR Doc. 2021-02574 Filed 2-8-21; 8:45 am]

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