Environmental Protection Agency

40 CFR Part 180


Ethaboxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of ethaboxam in or on Ginseng; Pepper/eggplant, subgroup 8–10B; Vegetable, cucurbit, group 9; and Vegetable, tuberous and corm, subgroup 1C. Valent USA Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 3, 2017. Objections and requests for hearings must be received on or before October 2, 2017, 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–2015–0676, 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: Mike Goodis, 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&site=ecfr&coll=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–2015–0676 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 October 2, 2017. 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–2015–0676, 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 whose disclosure is restricted by statute.
- 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 docket generally, is available at http://www.epa.gov/dockets.

II. Summary of Petitioned-For Tolerance

In the Federal Register of April 25, 2016 (81 FR 24044) (FRL–9944–86), 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 SF8383) by Valent USA Corporation, 1600 Riviera Avenue,
IV. DETERMINATION OF SAFETY

Committee on Economic Development

A. Summary of Analysis

The Committee on Economic Development finds that the determination of safety is based on a careful analysis of the available scientific data and expert judgment. The Committee recognizes that the determination of safety is a complex task and that there are uncertainties associated with it. The Committee recommends that the determination of safety be based on a comprehensive evaluation of all available information, including data from animal and human studies, epidemiological studies, and other relevant information.

B. Levels of Concern

The levels of concern are determined based on a careful analysis of the available scientific data and expert judgment. The levels of concern are used to identify the levels of concern that are of concern to human health and the environment. The levels of concern are developed based on a thorough evaluation of all available information, including data from animal and human studies, epidemiological studies, and other relevant information.

C. Risk Assessment

The risk assessment is based on a careful analysis of the available scientific data and expert judgment. The risk assessment is used to identify the levels of concern that are of concern to human health and the environment. The risk assessment is developed based on a thorough evaluation of all available information, including data from animal and human studies, epidemiological studies, and other relevant information.

D. Risk Characterization

The risk characterization is based on a careful analysis of the available scientific data and expert judgment. The risk characterization is used to identify the levels of concern that are of concern to human health and the environment. The risk characterization is developed based on a thorough evaluation of all available information, including data from animal and human studies, epidemiological studies, and other relevant information.

E. Risk Management

The risk management is based on a careful analysis of the available scientific data and expert judgment. The risk management is used to identify the levels of concern that are of concern to human health and the environment. The risk management is developed based on a thorough evaluation of all available information, including data from animal and human studies, epidemiological studies, and other relevant information.

F. Risk Communication

The risk communication is based on a careful analysis of the available scientific data and expert judgment. The risk communication is used to identify the levels of concern that are of concern to human health and the environment. The risk communication is developed based on a thorough evaluation of all available information, including data from animal and human studies, epidemiological studies, and other relevant information.
human risk assessment is shown in the Table of this unit.

### TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETHABOXAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT

<table>
<thead>
<tr>
<th>Exposure/scenario</th>
<th>Point of departure and uncertainty/safety factors</th>
<th>RID, PAD, LOC for risk assessment</th>
<th>Study and toxicological effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dietary (All Populations)</td>
<td>No appropriate endpoint attributable to a single dose identified.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Chronic dietary (All populations) | NOAEL = 5.5 mg/kg/day | Chronic RfD = 0.055 mg/kg/day | Combined Chronic/Carcinogenicity-Rat.
LOAEL = 16.4 mg/kg/day based on effects observed in the male reproductive organs (testes, epididymides, prostate, seminal vesicles). |
| Cancer (Oral, dermal, inhalation) | Classification: “Suggestive Evidence of Carcinogenicity”, based on an increased incidence of benign Leydig Cell tumors in males. Cancer risk has been assessed using a non-linear approach. | | |

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. FQPA SF = Food Quality Protection Act safety factor. UF = uncertainty factor. UF A = extrapolation from animal to human (interspecies). UF H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to ethaboxam, EPA considered exposure under the petitioned-for tolerances as well as all existing ethaboxam tolerances in 40 CFR 180.622. EPA assessed dietary exposures from ethaboxam in food as follows:
   
   i. Acute exposure. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.
   
   No such effects were identified in the toxicological studies for ethaboxam; therefore, a quantitative acute dietary exposure assessment is unnecessary.
   
   ii. Chronic exposure. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 2003–2008 U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). Tolerance-level residues and 100% crop treated were assumed for all crops. Empirical data indicate that residues of ethaboxam in processed grape (e.g., juice, raisins, etc.) and potato (e.g., flakes, chips, etc.) commodities are not expected to exceed the tolerance level for grapes or potatoes; therefore, no concentration factors were used in this analysis.
   
   iii. Cancer. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to ethaboxam. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., chronic exposure.
   
   iv. Anticipated residue and percent crop treated (PCT) information. EPA did not use anticipated residue and/or PCT information in the dietary assessment for ethaboxam. Tolerance-level residues and/or 100% CT were assumed for all food commodities.

2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for ethaboxam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of ethaboxam. Further information regarding EPA water exposure models in the dietary assessment can be found at http://www.epa.gov/oppefed1/models/water/index.htm.

   Based on the Pesticide in Water Calculator (PWC) v1.50 and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of ethaboxam for chronic exposures for non-cancer assessments are estimated to be 3.91 ppb for surface water and 7.4 ppb for ground water.

   Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 7.4 ppb was used to assess the contribution to drinking water.

3. From non-dietary exposure. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiteicides, and flea and tick control on pets).

Ethaboxam is not registered for any specific use patterns that would result in residential exposure.

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found ethaboxam to share a common mechanism of toxicity with any other substances, and ethaboxam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ethaboxam does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at http://www.epa.gov/pesticides/cumulative.

D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the
considered protective of developmental/ reproductive NOAEL, and thus is
Furthermore, the toxicology endpoint
been identified in both of the studies;
characterized and occur in the presence
effects observed in the studies are well
the degree of concern for prenatal and postnatal effects observed
in the studies is low based on the following: The developmental/offspring
effects observed in the studies are well characterized and occur in the presence
of maternal toxicity; a clear NOAEL has been identified in both of the studies;
and there are no residual uncertainties for pre-and/or postnatal toxicity.
Furthermore, the toxicology endpoint established for risk assessment is based
on a lower NOAEL than the reproductive NOAEL, and thus is
considered protective of developmental/offspring effects.
3. Conclusion. EPA has determined that reliable data show the safety of
infants and children would be adequately protected if the FQPA SF
were reduced to 1x. That decision is based on the following findings:
i. The toxicity database for ethaboxam is complete.
ii. There is no indication that
ethaboxam is a neurotoxic chemical and there is no need for a developmental
neurotoxicity study or additional UF to account for neurotoxicity.
iii. Although there is evidence of increased qualitative susceptibility in the
rat reproduction study, the offspring effects observed in the study are well
characterized and clear NOAELs/LOAELs have been identified in the
study for the effects of concern.
Additionally, the points of departure (PODs) selected for risk assessment are protective of potential offspring effects.
iv. There are no residual uncertainties identified in the exposure databases.
The dietary exposure assessments were performed based on 100% CT and
tolerance-level residues. EPA made conservative (protective) assumptions in the
ground and surface water modeling used to assess exposure to ethaboxam in
drinking water. These assessments will not underestimate the exposure and
risks posed by ethaboxam.
E. Aggregate Risks and Determination of Safety
EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and
chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime
probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the
estimated aggregate food, water, and residential exposure to the appropriate
PODs to ensure that an adequate MOE exists.
1. Acute risk. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking
water. No adverse effect resulting from a single oral exposure was identified
and no acute dietary endpoint was selected. Therefore, ethaboxam is not
expected to pose an acute risk.
2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to ethaboxam
from food and water will utilize 36% of the cPAD for children 1–2 years old
the population group receiving the greatest exposure. There are no residual uses for ethaboxam.
Short-term (and intermediate-term) aggregate exposure takes into account short-term (and intermediate-term) residential exposure plus chronic
exposure to food and water (considered to be a background exposure level).
Although short-term and intermediate-term adverse effects were identified,
ethaboxam is not registered for any use patterns that would result in short-term or intermediate-term residential exposure. Because there is no
residential exposure and chronic dietary exposure has already been assessed
under the appropriately protective cPAD (which is at least as protective as
the POD used to assess short-term or intermediate-term risk), no further
assessment of residential risk is necessary. EPA relies on the chronic
dietary risk assessment for evaluating short-term and intermediate-term risk for
ethaboxam.
As discussed in Unit III.A.,
EPA has determined that the chronic reference dose (cRFD) is protective of the
potential cancer effects. Because chronic exposure does not exceed the Agency’s
level of concern, EPA concludes that ethaboxam does not pose a cancer risk.
5. Determination of safety. Based on
these risk assessments, 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 ethaboxam residues.
IV. Other Considerations
A. Analytical Enforcement Methodology
Adequate enforcement methodology
Liquid Chromatography with tandem mass spectrometry (LC–MS/MS) is
available to enforce the tolerance expression.
The method 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: residumethods@
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 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.
MRLs have not been established by
Codex for residues of ethaboxam on the
commodities in this action.
C. Revisions to Petitioned-For
Tolerances
To reflect the correct commodity definitions, EPA revised the proposed
commodity listings for Potato (Tuberous and Corm Vegetable Subgroup 1C);
Peppers (Pepper/Eggplant Crop Subgroup 8–10B); and Cucurbit Vegetables (Crop Group 9) to Vegetable, tuberous and corm, subgroup 1C;
Pepper/eggplant, subgroup 8–10B; and
Vegetable, cucurb, group 9, respectively.
The petitioner requested that the
tolerances for Pepper/eggplant,
subgroup 8–10B be set at 0.6 ppm and
Ginseng be set at 0.09 ppm; however,
the Agency is establishing the tolerances
at 0.90 ppm and 0.10 ppm, respectively.
Based on Agency calculations using data
obtained from the submitted residue
studies. The Agency used the Organization for Cooperation and Development (OECD) maximum residue limit (MRL) calculation.
procedures to derive the recommended levels. For crop groups, and per EPA’s current policy, a tolerance level for each representative commodity was calculated separately, and then the maximum value within each crop group was selected as the tolerance level.

All of EPA’s tolerance levels are expressed to provide sufficient precision for enforcement purposes. This may include the addition of trailing zeros, as was the case for Vegetable, cucurbit, group 9 for which a tolerance of 0.3 ppm was proposed and a tolerance at 0.30 ppm is being established.

Finally, EPA is revising the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of ethaboxam not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of ethaboxam (N-(cyano-2-thienylmethyl)-4-ethyl-2-(ethlyamino)-5-thiazolecarboxamide), including its metabolites and degradates, in or on Ginseng at 0.10 ppm; Pepper/eggplant, subgroup 8–10B at 0.90 ppm; Vegetable, cucurbit, group 9 at 0.30 ppm; and Vegetable, tuberous and corm, subgroup 1C at 0.01 ppm. Compliance with the tolerance levels specified above is to be determined by measuring only ethaboxam (N-(cyano-2-thienylmethyl)-4-ethyl-2-(ethlyamino)-5-thiazolecarboxamide).

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: June 29, 2017.

Donna Davis,
Acting 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:


2. Section 180.622, paragraph (a) is revised to read as follows:

§ 180.622 Ethaboxam; tolerances for residues.

(a) General. Tolerances are established for residues of ethaboxam, including its metabolites and degradates, in or on the commodities listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only ethaboxam (N-(cyano-2-thienylmethyl)-4-ethyl-2-(ethlyamino)-5-thiazolecarboxamide) in or on the commodity.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ginseng</td>
<td>0.10</td>
</tr>
<tr>
<td>Grape</td>
<td>6.0</td>
</tr>
<tr>
<td>Pepper/eggplant subgroup 8–10B</td>
<td>0.90</td>
</tr>
<tr>
<td>Vegetable, cucurbit, group 9</td>
<td>0.30</td>
</tr>
<tr>
<td>Vegetable, tuberous and corm, subgroup 1C</td>
<td>0.01</td>
</tr>
</tbody>
</table>

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[FR Doc. 2017–16371 Filed 8–2–17; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Cyclaniliprole; Pesticide Tolerances and Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyclaniliprole in or on multiple commodities that are identified and discussed later in this document. ISK Biosciences Corporation requested these tolerances under the