	Diagnostic Code No.
* * * * * * *	
Malignant:	
* * * * * * *	
Hard and soft tissue	9918
* * * * * * *	
Nonunion:	
Mandible, confirmed by diagnostic imaging studies	9903
* * * * * * *	

[FR Doc. 2017–16132 Filed 8–2–17; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0676; FRL–9961–69]

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&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–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 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 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 5F8383) by Valent USA Corporation, 1600 Riviera Avenue,

Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR 180.622 be amended by establishing tolerances for residues of the fungicide ethaboxam, *N*-(cyano-2-thienylmethyl)-4-ethyl-2-(ethlyamino)-5-thiazolecarboxamide, in or on ginseng at 0.09 parts per million (ppm); Pepper/eggplant (Crop Subgroup 8–10B) at 0.6 ppm; Cucurbit Vegetables (Crop Group 9) at 0.3 ppm; and Tuberous and corm Vegetable Subgroup 1C at 0.01 ppm. That document referenced a summary of the petition prepared by Valent USA Corporation, 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 corrected proposed commodity definitions and revised certain proposed crop tolerances. 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 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 ethaboxam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with ethaboxam follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicology database for ethaboxam is complete. The male reproductive system is a target for ethaboxam, with alterations to the male reproductive organs as well as functional effects on male reproduction observed in several oral subchronic and chronic rat studies. In subchronic studies in rats, there were severe testicular alterations including small testes, decreased testicular weight and atrophy, abnormal spermatids in the testes, and interstitial cell hyperplasia. In the epididymis, there were small epididymides, decreased epididymal weights, abnormal spermatogenic cells, and absent spermatozoa. Decreased seminal vesicle and prostate weights were also observed. Effects were also seen after chronic exposure including decreased epididymal and seminal vesicle weights, seminiferous tubule atrophy, small/flaccid testes and epididymides, abnormal spermatogenic cells in the epididymal duct, absent sperm, epididymal vacuolation, and reduced colloid in the prostate. Fine vacuolation of the adrenal zona glomerulosa was also observed in both sexes in the rat studies, along with decreased body weight in females. There were no treatment-related male reproductive effects observed in mice, but there were effects seen in the liver. In mice, increased liver weights associated with centrilobular hypertrophy and liver histopathology (eosinophilic foci) were observed after chronic exposure. In dogs, decreased body weight and body weight gain, decreased thymus weights and thymus atrophy/involution, and hematopoiesis of the spleen were noted after subchronic exposure. No treatment-related effects were noted in dogs after chronic exposure. There is no concern for neurotoxicity or immunotoxicity after exposure to ethaboxam. No evidence of increased quantitative or qualitative susceptibility was seen in the developmental toxicity studies in rats and rabbits; however, increased qualitative susceptibility was seen in the rat reproduction study where decreased body weight, decreased viability, and delayed sexual maturation were seen in offspring animals in the presence of limited parental effects (decreased body weight and body weight gain). Ethaboxam is classified as having ''suggestive evidence of carcinogenic potential,'' based on an increased incidence of benign Leydig cell tumors in male rats. The Agency has determined that quantification of cancer risk using a non-linear approach (based on the POD of 5.5 mg/kg/day for establishing a chronic reference dose) would adequately account for all chronic toxicity since the POD is 6-fold lower than the lowest dose that induced tumors.

Specific information on the studies received and the nature of the adverse effects caused by ethaboxam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Ethaboxam. Human Health Risk Assessment for the Proposed First Food Uses on Fruiting Vegetables (Pepper/Eggplant Subgroup 8–10B), Cucurbit Vegetables (Group 9), Ginseng, and Potato (Tuberous and Corm Vegetable Subgroup 1C)'' at pages 27–32 in docket ID number EPA–HQ–OPP–2015–0676.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for ethaboxam used for

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All Populations)	No appropriate endpoint attributable to a single dose identified.		
Chronic dietary (All populations)	NOAEL= 5.5 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.055 mg/kg/day. cPAD = 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 drinking water models used in pesticide exposure 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, termiticides, 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

FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is evidence of increased qualitative susceptibility in the rat developmental and reproduction studies. Considering the overall toxicity profile and the doses and endpoints selected for risk assessment for ethaboxam, 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 UFs 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 food 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 residential uses for ethaboxam.

3. *Short-term and intermediate-term risk.* 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.

4. *Aggregate cancer risk for U.S. population.* 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 Chromotography with tandem mass spectrometrometry (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: *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 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, cucurbit, 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 of Economic 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:

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

■ 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-(ethylamino)-5-thiazolecarboxamide) in or on the commodity.

Commodity	Parts per million
Ginseng	0.10
Grape [1]	6.0
Pepper/eggplant subgroup 8–10B	0.90
Vegetable, cucurbit, group 9	0.30
Vegetable, tuberous and corm, subgroup 1C	0.01

[1] There is no U.S. registration as of September 27, 2006.

* * * * *

[FR Doc. 2017–16371 Filed 8–2–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0679; FRL–9963–02]

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