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 tolerances 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: October 25, 2019.

Daniel Rosenblatt,

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. In § 180.499(a):

■ a. Remove ''the following table'' and ''the following tolerance levels'' and add ''table 1 to this paragraph (a)'' and ''the tolerance levels in table 1 to this paragraph (a)'' in their places, respectively; and

■ b. Revise the table.

The revision reads as follows:

§ 180.499 Propamocarb; tolerances for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Guava	0.05
Leafy greens subgroup 4–16A	150
Starfruit	0.05
Tomato, paste	5.0
Vegetable, cucurbit, group 9	1.5
Vegetable, fruiting, group 8–10	4
Vegetable, tuberous and corm, subgroup 1C	0.3

* * * * *

[FR Doc. 2019–26130 Filed 12–4–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0162; FRL–10002–00]

Fenpyroximate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenpyroximate in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 5, 2019. Objections and requests for hearings must be received on or before February 3, 2020, 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–2018–0162, 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: Michael 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 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–2018–0162 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 February 3, 2020. 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–2018–0162, 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 14, 2018 (83 FR 40272) (FRL–9981–10), 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 8E8665) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of fenpyroximate determined by measuring only the sum of fenpyroximate, (E)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)methylene]amino]oxy]methyl] benzoate and its Z-isomer, (Z)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)methylene]amino]oxy]methyl] benzoate, calculated as the stoichiometric equivalent of fenpyroximate in or on the raw agricultural commodities: banana at 1.0 parts per million (ppm); blackeyed pea, succulent shelled at 0.40 ppm; broad bean, succulent shelled at 0.40 ppm; bushberry subgroup 13–07B at 3.0 ppm; caneberry subgroup 13–07A at 3.0 ppm; chickpea, succulent shelled at 0.40 ppm; cottonseed subgroup 20C at 0.10 ppm; cowpea, succulent shelled at 0.40 ppm; crowder pea, succulent shelled at 0.40 ppm; goa bean, pods, succulent shelled at 0.40 ppm; lablab bean, succulent shelled at 0.40 ppm; leaf petiole vegetable subgroup 22B at 4.0 ppm; lima bean, succulent shelled at 0.40 ppm; nut, tree, group 14–12 at 0.10 ppm; southern pea, succulent shelled at 0.40 ppm; soybean, edible, succulent shelled at 0.40 ppm; squash/cucumber subgroup 9B at 0.40 ppm; succulent bean, succulent shelled at 0.40 ppm; and velvet bean, succulent shelled at 0.40 ppm. The petition also requested to remove the established tolerances for residues of fenpyroximate in or on the following raw agricultural commodities: Bean, snap, succulent at 0.40 ppm; cotton, undelinted seed at 0.10 ppm; cucumber at 0.40 ppm; nut, tree, group 14 at 0.10 ppm; and pistachio at 0.10 ppm. That document referenced a summary of the petition prepared by Nichino America, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Pursuant to its authority in FFDCA section 408(d)(4)(A)(i), EPA is establishing tolerances that vary slightly from what the petitioner requested. The reasons for these changes are located 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 fenpyroximate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenpyroximate 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.

Following repeated oral exposures to fenpyroximate, general systemic toxicity was observed (no specific target organ/tissue identified). The most common effect observed across studies and species was decreased body weight. In dogs, clinical signs, such as diarrhea, torpor, and emaciation, and slight bradycardia were observed at similar or higher doses than those that elicited adverse decreases in body weight.

In the rat neurotoxicity battery, effects in the subchronic neurotoxicity study were limited to decreased body weights at the highest doses tested (16–18 mg/kg/day). In the acute neurotoxicity study, decreased motor activity (both sexes) and auditory startle response (females only) were observed in the absence of neuropathological findings. There were no effects seen in the delayed acute neurotoxicity study in hens up to the limit dose (5,000 mg/kg).

Following repeated dermal exposure, body weight decrements were only observed at the limit dose (1,000 mg/kg/day) in the presence of clinical signs consisting of red nose and mouth/nasal discharge in females. Increased liver weights and hepatocellular necrosis were also reported in females.

In the 4-week inhalation study in rats, clinical signs (rales and labored

breathing), increased lung weights, and histopathological findings in the nasal turbinates (squamous metaplasia and atrophy of respiratory and/or olfactory mucosa) were observed. Body-weight decrements were not observed following repeated exposure via the inhalation route.

There was no evidence of increased susceptibility following fenpyroximate exposure. There were no effects observed in the rat and rabbit developmental toxicity studies up to the highest doses tested (25 mg/kg/day and 5 mg/kg/day in the rat and rabbit, respectively). In the reproduction toxicity study, offspring and parental effects (decreased body weights for both lifestages) were observed at the same dose.

Fenpyroximate is classified as ''not likely to be carcinogenic to humans'' based on lack of evidence of carcinogenicity in rats and mice.

Specific information on the studies received and the nature of the adverse effects caused by fenpyroximate 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 the document titled ''Fenpyroximate: Human Health Draft Risk Assessment for Registration Review and a Petition to Establish Tolerances for Residues in/on the Banana; Leaf Petiole Vegetable Subgroup 22B; Caneberry Subgroup 13–07A; Bushberry Subgroup 13–07B; Squash/Cucumber Subgroup 9B; and Succulent Shelled Beans; and Crop Group Conversions for Nut, Tree, Group 14–12; and Cottonseed Subgroup 20C'' on pages 37–41 in docket ID number EPA–HQ–OPP–2018–0162.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide.*

A summary of the toxicological endpoints for fenpyroximate used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FENPYROXIMATE 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)	NOAEL = 37.5 mg/kg/day UF_A = 10X. UF_H = 10X FQPA SF = 1X	Acute RfD = 0.375 mg/kg/day aPAD = 0.375 mg/kg/day.	*Acute neurotoxicity study—rat.* LOAEL = 150 mg/kg based on decreased motor activity (total activity counts and total time spent in movement) in both sexes, a reduction in auditory startle response in females at 24 hours post dose, and mild dehydration in males.
Chronic dietary (All populations)	NOAEL= 1.0 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.01 mg/kg/day. cPAD = 0.01 mg/kg/day.	*Combined chronic/carcinogenicity study—rat.* LOAEL = 3.1/3.8 (M/F) based on decreased body-weight gain (Note: corresponding >10% decrease in absolute body weight observed).
Cancer (Oral, dermal, inhalation).	Classification: ''Not likely to be carcinogenic to humans.''		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. 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 fenpyroximate, EPA considered exposure under the petitioned-for tolerances as well as all existing fenpyroximate tolerances in 40 CFR 180.566. EPA assessed dietary exposures from fenpyroximate 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.

Such effects were identified for fenpyroximate. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA; 2003–2008). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues using default processing factors for all commodities excluding apple, pear, and grape juice (0.11X); grape, raisin (2.7X); orange, grapefruit, tangerine, lemon, and lime juice (0.06X); tomato paste (1.0X) and puree (1.0X); dried plum (1.0X); and peppermint and spearmint oil (0.08X).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA (2003–2008). As to residue levels in food, EPA used percent crop treated estimates for some commodities and tolerance-level residues using default

processing factors for all commodities excluding apple, pear, and grape juice (0.11X); grape, raisin (2.7X); orange, grapefruit, tangerine, lemon, and lime juice (0.06X); tomato paste (1.0X) and puree (1.0X); dried plum (1.0X); and peppermint and spearmint oil (0.08X).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fenpyroximate does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

100 PCT was assumed for the acute analyses. The chronic analysis incorporated the following average PCT: Apples, 5.0%; apricots, 1.0%; avocados, 1.0%; beans (fresh), 1.0%; cantaloupes, 2.5%; cherries, 5.0%; corn, 1.0%; cotton, 1.0%; grapefruit, 10%; grapes, table, 2.5%; grapes, raisin, 5.0%; grapes, wine, 5.0%; lemons, 2.5%; oranges, 10%; peaches, 1.0%; pears, 10%; pecans, 5.0%; peppers, 10%; plums, 5.0%; prunes, 1.0%; strawberries, 5.0%; tangerines, 5.0%; tomatoes, 1.0%; and watermelons, 1.0%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figures for each existing use are derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which fenpyroximate may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for fenpyroximate in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenpyroximate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide Water Calculator (PWC) and Pesticides in Flooded Applications Model (PFAM), the estimated drinking water concentrations (EDWCs) of fenpyroximate for acute exposures are estimated to be 18.8 parts per billion (ppb) for surface water and 43.92 ppb for ground water, and for chronic exposures are estimated to be 4.74 ppb for surface water and 43.42 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 43.92 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 43.42 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).

Fenpyroximate 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 fenpyroximate to share a common mechanism of toxicity with any other substances, and fenpyroximate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fenpyroximate 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 website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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 was no evidence of increased quantitative or qualitative susceptibility in the developmental toxicity studies in rabbits or rats or the reproduction toxicity study in rats.

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 fenpyroximate is complete.

ii. Although decreased motor activity and startle response were observed in the acute neurotoxicity study in rats, concern is low since: (1) There was no evidence of neurotoxicity in the rest of the fenpyroximate toxicological database, including the subchronic neurotoxicity study and the acute neurotoxicity study in hens; (2) clear NOAEL/LOAEL values were identified for the effects observed in the rat acute neurotoxicity study; and (3) the selected endpoints are protective of the observed effects. Therefore, there is no residual uncertainty concerning neurotoxicity and no need to require a developmental neurotoxicity study.

iii. There is no evidence that fenpyroximate results in increased susceptibility *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary analysis is unrefined for acute dietary exposures, partially refined for chronic dietary exposures, and both acute and chronic dietary analyses incorporated upper bound modeled drinking water residues. Therefore, the dietary assessment is unlikely to underestimate exposure.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenpyroximate will occupy 8.7% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenpyroximate from food and water will utilize 60% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for fenpyroximate.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, fenpyroximate is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- or intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term 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- or intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for fenpyroximate.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fenpyroximate is not expected to pose a cancer risk to humans.

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 fenpyroximate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography method with nitrogen/phosphorus detection (GC/NPD), Method S19) is available to enforce the tolerance expression. Method S19 has passed an Agency validation and has a limit of quantitation (LOQ) of 0.05 ppm for the combined residues of fenpyroximate and M–1 in snap beans and avocados. A data-gathering liquid chromatography/mass spectroscopy/mass spectroscopy (LC/MS/MS) method is also available.

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.

Codex MRLs are established for residues of fenpyroximate *per se* in tree nuts at 0.05 ppm, squash at 0.06 ppm, and cucumber at 0.3 ppm. These are lower than the tolerances that are being established in the United States. Harmonization with the Codex MRLs is not possible because the U.S. tolerance expression includes an additional isomer and the U.S. use patterns require higher numerical values.

C. Revisions to Petitioned-For Tolerances

EPA is establishing all the tolerances at different levels than petitioned for in order to be consistent with the Agency's rounding class practice, which is based on the rounding procedures of the Organisation for Economic Co-operation

and Development. Also, although the petitioner has petitioned for the removal of the existing tolerance for residues in ''Bean, snap, succulent,'' this tolerance is being retained in order to support the currently labeled use on this crop.

V. Conclusion

Therefore, tolerances are established for residues of fenpyroximate in or on Banana at 1 ppm; Blackeyed pea, succulent shelled at 0.4 ppm; Broad bean, succulent shelled at 0.4 ppm; Bushberry subgroup 13–07B at 3 ppm; Caneberry subgroup 13–07A at 3 ppm; Chickpea, succulent shelled at 0.4 ppm; Cottonseed subgroup 20C at 0.1 ppm; Cowpea, succulent shelled at 0.4 ppm; Crowder pea, succulent shelled at 0.4 ppm; Goa bean, pods, succulent shelled at 0.4 ppm; Lablab bean, succulent shelled at 0.4 ppm; Leaf petiole vegetable subgroup 22B at 4 ppm; Lima bean, succulent shelled at 0.4 ppm; Nut, tree, group 14–12 at 0.1 ppm; Southern pea, succulent shelled at 0.4 ppm; Soybean, edible, succulent shelled at 0.4 ppm; Squash/cucumber subgroup 9B at 0.4 ppm; Succulent bean, succulent shelled at 0.4 ppm; and Velvet bean, succulent shelled at 0.4 ppm.

Additionally, the following existing tolerances are removed as unnecessary due to the establishment of the above tolerances: Cotton, undelinted seed; Cucumber; Nut, tree, group 14; and Pistachio.

VI. Statutory and Executive Order Reviews

This action establishes and modifies 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), 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 tolerances 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: November 19, 2019.

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. In § 180.566, amend the table in paragraph (a)(1) as follows:
■ a. Add alphabetically the entries ''Banana''; ''Blackeyed pea, succulent shelled''; ''Broad bean, succulent shelled''; ''Bushberry subgroup 13–07B''; ''Caneberry subgroup 13–07A''; ''Chickpea, succulent shelled''; and ''Cottonseed subgroup 20C'';
■ b. Remove the entry for ''Cotton, undelinted seed'';
■ c. Add alphabetically the entries ''Cowpea, succulent shelled'' and ''Crowder pea, succulent shelled'';
■ d. Remove the entry for ''Cucumber'';
■ e. Add alphabetically the entries ''Goa bean, pods, succulent shelled''; ''Lablab bean, succulent shelled''; ''Leaf petiole vegetable subgroup 22B''; ''Lima bean, succulent shelled''; and ''Nut, tree, group 14–12'';
■ f. Remove the entries for ''Nut, tree, group 14'' and ''Pistachio''; and
■ g. Add alphabetically the entries ''Southern pea, succulent shelled''; ''Soybean, edible, succulent shelled''; ''Squash/cucumber subgroup 9B''; ''Succulent bean, succulent shelled''; and ''Velvet bean, succulent shelled''.

The additions read as follows:

§ 180.566 Fenpyroximate; tolerances for residues.

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

Commodity	Parts per million
* * * * *	
Banana	1
* * * * *	
Blackeyed pea, succulent shelled	0.4
Broad bean, succulent shelled	0.4
Bushberry subgroup 13–07B	3
Caneberry subgroup 13–07A	3
* * * * *	
Chickpea, succulent shelled	0.4
* * * * *	
Cottonseed subgroup 20C	0.1
Cowpea, succulent shelled	0.4

Commodity	Parts per million
Crowder pea, succulent shelled	0.4
* * * * *	
Goa bean, pods, succulent shelled	0.4
* * * * *	
Lablab bean, succulent shelled	0.4
Leaf petiole vegetable subgroup 22B	4
Lima bean, succulent shelled	0.4
* * * * *	
Nut, tree, group 14–12	0.1
* * * * *	
Southern pea, succulent shelled	0.4
Soybean, edible, succulent shelled	0.4
* * * * *	
Squash/cucumber subgroup 9B	0.4
* * * * *	
Succulent bean, succulent shelled	0.4
* * * * *	
Velvet bean, succulent shelled	0.4

* * * * *

[FR Doc. 2019–26131 Filed 12–4–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0644; FRL–10000–97]

Etoxazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of etoxazole in or on beet, sugar, roots and beet, sugar, leaves. The Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 5, 2019. Objections and requests for hearings must be received on or before February 3, 2020 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–2018–0644, 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: Michael 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 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–2018–0644 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 February 3, 2020. 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–2018–0644, 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 March 18, 2018 (84 FR 9737) (FRL–9989–71), 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 8E8701) by IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W. Princeton, NJ 08540. The petition requested that 40 CFR part 180.593 be amended by establishing tolerances for residues of the insecticide etoxazole, (2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole), in or on the following sugar beet commodities: Roots at 0.02 parts per million (ppm); dried pulp at 0.04 ppm; and leaves at 1 ppm. In addition, the petition requested tolerances for etoxazole residues in or on the leaves of many other commodities at 1 ppm. That document referenced a summary of the petition prepared by Valent U.S.A. Corporation,