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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: December 6, 2012.

**Lois Rossi,**

*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 180.639 is amended as follows:

■ a. In paragraph (a)(1) revise the introductory text and the entries for ''apple, wet pomace,'' and ''fruit, pome, group 11.''

■ b. Revise the introductory text to paragraph (d).

The revised text reads as follows:

**§ 180.639 Flubendiamide; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of flubendiamide, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only flubendiamide $N^2$-[1, 1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-$N^1$-[2-methyl-4- [1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide, in or on the following commodities:

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Apple, wet pomace | 5.0 |
| * * * * * | |
| Fruit, pome, group 11 | 1.5 |

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of flubendiamide, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only flubendiamide N2-[1, 1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-N1-[2-methyl-4- [1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1, 2-benzenedicarboxamide, in or on the following commodities:

* * * * *

[FR Doc. 2012–29979 Filed 12–11–12; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2011–0541; FRL–9360–3]**

### Fenpyroximate; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of the insecticide fenpyroximate in or on multiple commodities identified and discussed later in this document. In addition, this regulation removes established tolerances for certain commodities/groups superseded by this action. The 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 12, 2012. Objections and requests for hearings must be received on or before February 11, 2013, 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–2011–0541, is available either electronically through *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, 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:** Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; email address: *jackson.sidney@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- 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://ecfr.gpoaccess.gov/cgi/t/*

*text/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–2011–0541 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 11, 2013. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0541, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 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.htm.* 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 Wednesday, September 7, 2011 (76 FR 55329) (FRL–8886–7), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7881) by IR–4, Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540; and on Wednesday, May 2, 2012 (77 FR 25954) (FRL–9346–1) for PP 1F7902 by Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808. The petitions requested that 40 CFR 180.566 be amended by establishing tolerances for residues of the insecticide fenpyroximate, (*E*)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl) methyene]amino]oxy]methyl]benzoate and its Z-isomer, (*Z*)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methylene]amino]oxy] methyl]benzoate, in or on avocado at 0.2 parts per million (ppm); bean, snap at 0.4 ppm; canistel at 0.2 ppm; cucumber at 0.25 ppm; fruit, citrus, group 10–10 at 0.6 ppm; fruit, pome, group 11–10 at 0.4 ppm; mango at 0.2 ppm; papaya 0.2 ppm; sapodilla at 0.2 ppm; sapote, black at 0.2 ppm; sapote, mamey at 0.2 ppm; star apple at 0.2 ppm; tea, plucked leaves at 15 ppm; and vegetable, fruiting, group 8–10 at 0.2 ppm; corn, field, grain at 0.02 ppm; corn, field, forage/silage at 2.0 ppm; corn, field, stover at 7.0 ppm; corn, field, aspirated fractions at 2.0 ppm; corn, pop, grain at 0.02 ppm; corn, pop, forage/silage at 2.0 ppm; corn, pop, stover at 7.0 ppm; and corn, pop, aspirated fractions at 2.0 ppm. In addition, petition 1E7881 proposed to remove established tolerances in or on the raw agricultural commodities/groups: Fruit, citrus, group 10 at 0.60 ppm; fruit, pome, group 11 at 0.40 ppm; and vegetable, fruiting, group 8 at 0.20 ppm. The notices referenced a summary of the respective petition prepared by Nichino America, Inc., the registrant, available in the docket, *http://www.regulations.gov.* There were no comments received in response to these notices of filing. Based upon review of the data supporting the petitions, EPA is establishing tolerance levels for certain commodities other than the proposed level. 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 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 their 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.

Fenpyroximate induced moderate acute oral and inhalation toxicity in rats. It exhibited low dermal acute toxicity and was neither a skin nor eye irritant. Fenpyroximate was a slight to moderate sensitizer by the maximization test method. Subchronic and chronic oral exposures to fenpyroximate resulted in overall systemic toxicity (no specific target organ/tissue identified). The most sensitive species tested was the dog. The effects reported in the dog included slight bradycardia, deficits in food consumption, body weight, body-weight gain, and an increased incidence of emesis and diarrhea. Emaciation and torpor (sluggish inactivity) were reported in female dogs at lower dose levels than males. The highest dose tested in the dog (50 milligrams/kilogram/day (mg/kg bw/day)) resulted in first- and second-degree heart block, increased urea concentration, decreased glucose, and altered plasma electrolyte levels among other signs of toxicity. In subchronic and chronic studies with rats, the primary effect was decreased body-weight gain in both sexes with hematological changes (e.g., higher counts of red blood cells) at higher doses.

In a rat prenatal developmental toxicity study, a fenpyroximate dose level that marginally affected maternal body weight and food consumption also resulted in an increased litter incidence of increased thoracic ribs, indicating increased prenatal (qualitative) susceptibility. In the rabbits, there no developmental effects reported at the levels tested. In the rat two-generation reproductive toxicity study, there was no indication of increased pre- or post-natal susceptibility; maternal toxicity (decreased body-weight) and offspring toxicity (decreased lactational weight gain in both generations) occurred at the same dose. Reproductive parameters were not affected.

Acute and subchronic neurotoxicity studies in the rat show no evidence that fenpyroximate specifically targets the nervous system. In the acute neurotoxicity study, neurotoxicity signs such as decreases in motor activity occurred in the presence of other effects including decreases in body weight and food consumption, and in the absence of neuropathology. Similar results were noted in a delayed acute neurotoxicity study in the hen where no effects (neurotoxic or otherwise) were reported. The results of the rat subchronic neurotoxicity study did not indicate any neurotoxicity-specific effects; deficits in body weight and food consumption were the main effects reported. Effects reported in a rat immunotoxicity study were limited to decreased body-weight gain, indicating the fenpyroximate does not directly target the immune system.There is no evidence of carcinogenic potential for fenpyroximate based on the results of carcinogenicity studies via the oral route in either the rats or mice resulting in the carcinogenicity classification of ''not likely'' to be carcinogenic to humans. Genotoxicity studies including mutagenicity did not demonstrate any genotoxic potential resulting from fenpyroximate exposure.

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 document: ''Fenpyroximate. Human-Health Risk Assessment for (1) Proposed Section 3 Uses on Cucumber, Snap Bean, Avocado, Black Sapote, Canistel, Mamey Sapote, Mango, Papaya, Sapodilla, Star Apple, Corn (Field, Pop, Silage, and Grown for Seed); (2) Updated Tolerances for Citrus Fruit-Group 10–10, Pome Fruit Group 11–10, and Fruiting Vegetable Group 8–10; (4) the Establishment of a Tolerance on Imported Tea; (3) Increase in Maximum Seasonal Application Rate on Mint; and (4) Proposed Label Amendment to Include Aerial Applications to Existing Uses on Citrus in Texas, Melons, Fruiting Vegetables, and Snap Beans,'' dated April 16, 2012 at p. 32 in docket ID number EPA–HQ–OPP–2011–0541–0005.

*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 fenpyroximate used for human risk assessment is shown in the following Table.

TABLE—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 (Females 13–50 years of age). | NOAEL = 5.0 mg/kg bw.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | aRfD = .....<br>aPAD = 0.05 mg/kg bw | Prenatal Developmental Toxicity Study—Rat. LOAEL = 25 mg/kg/day based on increase in the fetal incidence of additional thoracic ribs. |
| Acute dietary (General population including infants and children). | NOAEL = 37.5 mg/kg bw.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | aRfD = .....<br>aPAD = 0.375 mg/kg bw | Acute Neurotoxicity Study—Rat.<br>LOAEL = 150 mg/kg bw based on decreased motor activity (total activity counts and total time spent in movement) in both sexes, and a reduction in auditory startle response in females at 24 hours post dose, and mild dehydration in males. |
| Chronic dietary (All populations) | NOAEL = 5.0 mg/kg/day.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | cRfD = .....<br>cPAD = 0.05 mg/kg/day | Chronic toxicity—Dogs.<br>LOAEL = 15 mg/kg/day based on an increased incidence of bradycardia, diarrhea, and decreases in cholesterol, body-weight gain, and food consumption (M); vomiting, diarrhea, excess salivation and decrease cholesterol in females. |

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FENPYROXIMATE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

| Exposure/scenario | Point of departure and uncertainty/ safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|---|---|---|---|
| Cancer (Oral, dermal, inhalation). | Classification: ''Not likely to be carcinogen.'' | | |

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. mg/kg bw = milligram/kilogram of body weight. 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) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed 100 percent crop treated (PCT), tolerance-level residues for all commodities, DEEM™ (ver. 7.81) default processing factors for all commodities except for apple, pear, and grape juice; raisin; orange, grapefruit, tangerine, lemon and lime juice; tomato paste and puree; and peppermint and spearmint oil. Chemical-specific data were used to calculate empirical processing factors for these commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed 100 PCT, tolerance-level residues for all commodities, and DEEM™ (ver. 7.81) default processing factors for most commodities except for apple, pear, and grape juice; raisin; orange, grapefruit, tangerine, lemon and lime juice; tomato paste and puree; and peppermint and spearmint oil. Chemical-specific data were used to calculate empirical processing factors for these commodities.

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 percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for fenpyroximate. Tolerance-level residues and 100 PCT 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 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://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST), a Provisional Cranberry Model and Screening Concentration in Ground Water (SCI–GROW) model, the Agency calculated conservative estimated drinking water concentrations (EDWCs) of fenpyroximate. Tier 1 EDWCs reflect exposure in drinking water to the residues of fenpyroximate and its isomer/degradate, its *cis* isomer M–1, and its carboxylic acid M–3, all of which are assumed to have similar toxicity.

For acute exposures, EDWCs are estimated to be 43 parts per billion (ppb) for surface water and 0.27 ppb for ground water.

For chronic exposures, EDWCs are estimated to be 8.6 ppb for surface water and 0.27 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 43 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 8.6 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 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 prenatal (qualitative) susceptibility in a rat prenatal developmental toxicity study. A dose level that marginally affected maternal body weight and food consumption also resulted in an increased litter incidence of increased thoracic ribs. However, concern for pre-natal and post-natal toxicity to fenpyroximate is low because (1) there was a clear NOAEL in the rat prenatal developmental toxicity study; (2) the NOAEL for this developmental study is being used as POD for the acute dietary risk assessment for the population of concern—females 13–49 years old; (3) in the rabbit, there were no developmental effects reported at the levels tested, and (4) in the rat two-generation reproductive toxicity study, there was no indication of increased pre- or post-natal susceptibility.

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 for all exposure scenarios. That decision is based on the following findings:

i. The toxicity database for fenpyroximate is complete.

ii. There is no indication that fenpyroximate is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is evidence that fenpyroximate results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. Increased (qualitative) prenatal susceptibility was seen following oral exposures in the rat developmental toxicity study. However, for the reasons noted in Unit III.D.2., the concern is low.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessment utilizes tolerance-level residues (established or recommended) and 100 PCT for all proposed/established commodities. By using these assumptions, the acute and chronic exposures/risks will not be underestimated. The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters, which are designed to provide conservative, health-protective, high-end estimates of water concentrations that will not likely be exceeded. There are no registered or proposed uses that will result in residential exposure. These assessments will not underestimate the exposure and risks posed by fenpyroximate.

*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 3.6% 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 9.0% 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 risks.* 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).

Short- and intermediate-term adverse effects were identified; however, fenpyroximate is not registered for any use patterns that would result in short- and intermediate-term residential exposure. Short- and intermediate-term risks are assessed based on short- and intermediate term residential exposures plus chronic dietary exposure. Because there are no short- and 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- and intermediate-term risks), no further assessments of short- and intermediate-term risks are necessary. EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risks 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 with nitrogen/phosphorus detection (GC/NPD), Method S19, has passed an Agency validation) and is available to enforce the tolerance expression.

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

*B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex 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/on several crop commodities. Harmonization with the Codex MRLs is not possible because the U.S. tolerance expressions include both the parent fenpyroximate and additional metabolites/isomers. However, the Agency is lowering the pome fruit tolerance from 0.40 ppm to 0.30 ppm in order to harmonize with the Codex MRL level. Similarly, based on recently

submitted residue data on citrus, EPA is lowering the existing citrus fruit tolerance from 0.60 ppm to 0.50 ppm in order to harmonize with the Codex MRL level.

*C. Revisions to Petitioned-For Tolerances*

EPA modified/revised certain IR–4 proposed tolerances based on results from the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures in order to determine appropriate tolerance levels from available U.S. residue data. The proposed tolerance at 0.20 ppm for avocado, black sapote, mamey sapote, canistel, mango, papaya, sapodilla, and star apple was lowered to 0.15 ppm. Similarly, proposed tolerances for cucumber and tea, dried were increased from 0.25 ppm to 0.40 ppm, and from 15 ppm to 20 ppm, respectively. The submitted residue data for corn grain were not entered into the tolerance spreadsheet for OECD calculations because all treated samples showed combined fenpyroximate residues below the level of quantitation (LOQ) of 0.02 ppm. However, based on available residue data, EPA established a tolerance for grain, aspirated fractions at 0.40 ppm to replace proposed tolerances for corn, field aspirated fractions at 2.0 ppm and corn, pop aspirated fractions at 2.0 ppm. In addition, EPA established a tolerance for corn, refined oil at 0.05 ppm. Also, tolerances for fruit, citrus crop group 10–10 and fruit, pome, group 11–10 were reduced to 0.50 ppm and 0.30 ppm, respectively, in order to harmonize with Codex MRL.

The Agency is deleting the existing tolerance for okra at 0.20 ppm since it is included in vegetable, fruiting group 8–10 established by this action. In addition, EPA corrected commodity definitions to comply with current EPA policy as follows: ''corn, field, forage/silage'' and ''corn, pop, forage/silage'' were corrected to ''corn, field, forage'' and ''corn, pop, forage,'' respectively, and ''tea, plucked leaves'' was corrected to ''tea, dried.''

Finally, EPA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of fenpyroximate 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 the insecticide fenpyroximate, (*E*)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methyene]amino]oxy]methyl] benzoate and its Z-isomer, (*Z*)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methylene] amino]oxy]methyl]benzoate, including its metabolites and degradates in or on avocado at 0.15 ppm, bean, snap, succulent at 0.40 ppm, canistel at 0.15 ppm, corn, field, grain at 0.02 ppm, corn, field, forage at 2.0 ppm, corn, field, stover at 7.0 ppm, corn, pop, grain at 0.02 ppm, corn, pop, forage at 2.0 ppm, corn, pop, stover at 7.0 ppm, corn, field, refined oil at 0.05 ppm, grain, aspirated fractions at 0.40 ppm, cucumber at 0.4 ppm, fruit, citrus, group 10–10 at 0.50 ppm, fruit, pome, group 11–10 at 0.30 ppm, mango at 0.15 ppm, papaya 0.15 ppm, sapodilla at 0.15 ppm, sapote, black at 0.15 ppm, sapote, mamey at 0.15 ppm, star apple at 0.15 ppm, tea, dried at 20 ppm, and vegetable, fruiting, group 8–10 at 0.20 ppm.

Lastly, EPA is removing the entries for ''fruit, citrus, group 10,'' ''fruit, pome, group 11,'' ''okra'' and ''vegetable, fruiting, group 8'' from the table at 40 CFR 180.566(a)(1) since ''new tolerances'' established by this action will supersede the existing tolerances.

## VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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 of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

## VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: December 4, 2012.

**Lois Rossi,**

*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 revise paragraph (a)(1), and the introductory texts of paragraphs (a)(2), (a)(3) and (b) to read as follows:

**§ 180.566 Fenpyroximate; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of the insecticide fenpyroximate, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only the sum of fenpyroximate, (*E*)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methylene]amino]oxy] methyl]benzoate and its Z-isomer, (*Z*)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methylene] amino]oxy]methyl]benzoate, calculated as the stoichiometric equivalent of fenpyroximate.

| Commodity | Parts per million |
|---|---|
| Almond, hulls | 3.0 |
| Avocado | 0.15 |
| Bean, snap, succulent | 0.40 |
| Berry, low growing, subgroup 13–07G | 1.0 |
| Canistel | 0.15 |
| Citrus, dried pulp | 2.5 |
| Citrus, oil | 10 |
| Corn, field, forage | 2.0 |
| Corn, field, grain | 0.02 |
| Corn, field, refined oil | 0.05 |
| Corn, field, stover | 7.0 |
| Corn, pop, forage | 2.0 |
| Corn, pop, grain | 0.02 |
| Corn, pop, stover | 7.0 |
| Cotton, gin byproducts | 10 |
| Cotton, undelinted seed | 0.10 |
| Cucumber | 0.40 |
| Fruit, citrus, group 10–10 | 0.50 |
| Fruit, pome, group 11–10 | 0.30 |
| Grain, aspirated fractions | 0.40 |
| Grape | 1.0 |
| Hop, dried cones | 10 |
| Mango | 0.15 |
| Melon subgroup 9A | 0.10 |
| Nut, tree, group 14 | 0.10 |
| Papaya | 0.15 |
| Peppermint, tops | 7.0 |
| Pistachio | 0.10 |
| Sapodilla | 0.15 |
| Sapote, black | 0.15 |
| Sapote, mamey | 0.15 |
| Spearmint, tops | 7.0 |
| Star, apple | 0.15 |
| Tea, dried [1] | 20 |
| Vegetable, fruiting, group 8–10 | 0.20 |

[1] There are no U.S. Registrations.

(2) Tolerances are established for residues of the insecticide fenpyroximate, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only the sum of fenpyroximate, (*E*)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methylene]amino]oxy] methyl]benzoate and its metabolites (*E*)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methyleneaminooxymethyl]benzoic acid and (*E*)-1,1-dimethylethyl-2-hydroxyethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methylene] amino]oxy]methyl]benzoate, calculated as the stoichiometric equivalent of fenpyroximate.

* * * * *

(3) Tolerances are established for residues of the insecticide fenpyroximate, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only the sum of fenpyroximate, (*E*)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methylene]amino]oxy] methyl]benzoate and its metabolite (*E*)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methyleneaminooxymethyl]benzoic acid, calculated as the stoichiometric equivalent of fenpyroximate.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the insecticide fenpyroximate, including its metabolites and degradates in or on the commodities in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only the sum of fenpyroximate, (*E*)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl) methylene]amino] oxy]methyl]benzoate and its Z-isomer, (*Z*)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl) methylene]amino]oxy]methyl]benzoate, calculated as the stoichiometric equivalent of fenpyroximate.

* * * * *

[FR Doc. 2012–29900 Filed 12–11–12; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2011–1012; FRL–9365–6]**

### Pyriproxyfen; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of pyriproxyfen 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 12, 2012. Objections and requests for hearings must be received on or before February 11, 2013, 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–2011–1012, 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), EPA West 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:** Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; email address: *ertman.andrew@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