



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2016-0307; FRL-9963-22]

### Fenpyroximate; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation increases existing tolerances for residues of fenpyroximate in or on dried citrus pulp, citrus oil, and the citrus fruit group 10-10. Nichino America, Inc. requested these tolerance increases under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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-2016-0307, 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 Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](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-2016-0307 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 *[insert date 60 days after date of publication in the **Federal Register**]*. 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-2016-0307, 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 29, 2016 (81 FR 59165) (FRL-9950-22), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F8465) by Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808. The petition requested to increase the tolerances in 40 CFR 180.566 for residues of the insecticide fenpyroximate in or on fruit, citrus, group 10–10 to 1.0 parts per million (ppm), citrus dried pulp to 4.0 ppm, and citrus oil to 14 ppm. That document referenced a summary of the petition

prepared by Nichino America, Inc., the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the level of the citrus oil tolerance from 14 ppm to 15 ppm. The reason for this change is 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 its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The effects following repeated oral exposures to fenpyroximate were based on 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 milligram/kilogram bodyweight/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 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 were no developmental effects reported at the levels tested. In the rat two-generation reproductive toxicity study, maternal toxicity (decreased body weight) and offspring toxicity (decreased lactational weight gain in both generations) occurred at the same dose.

There is no evidence that fenpyroximate specifically targets the nervous or immune system based on the results of recently submitted studies. 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. Similarly, the effects reported in a rat immunotoxicity study were limited to decreased body-weight gain.

In a 21-day dermal toxicity study in rats, there were clinical signs in females consisting of red nose and mouth/nasal discharge, decreased body weights, body-weight gains, and food consumption in males and females. There were also increased liver weights and hepatocellular necrosis reported in females.

In a 4-week rat inhalation study, treatment-related effects included clinical observations (labored breathing and rales), increased lung weights, decreases in body-weight gain and food consumption, and changes in hematology parameters (increased

counts of erythrocytes and leukocytes). There were also histopathology findings in the nasal passage mucosa consisting of atrophy and squamous metaplasia.

Fenpyroximate was classified as “not likely to be carcinogenic to humans” based on the results of rat and mouse carcinogenicity studies. Genotoxicity studies including mutagenicity did not demonstrate any genotoxic potential associated with fenpyroximate.

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 Risk Assessment for Proposed Section 3 Uses on Stone Fruits (Group 12-12), Tuberous and Corm Vegetables (Subgroup 1C), and Small Vine Climbing Fruits Except Kiwifruit (Subgroup 13-07F)*” on page 28 in docket ID number EPA-HQ-OPP-2016-0307.

#### *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-pesticides>.

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**

<b>Exposure/Scenario</b>	<b>Point of Departure and Uncertainty/Safety Factors</b>	<b>RfD, PAD, LOC for Risk Assessment</b>	<b>Study and Toxicological Effects</b>
Acute dietary (Females 13-50 years of age)	NOAEL = 5.0 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 0.05 mg/kg/day aPAD = 0.05 mg/kg/day	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/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 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 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 UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day	Chronic toxicity - Dog  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.]
Cancer (Oral, dermal, inhalation)	Classification: “Not likely to be carcinogen,” cancer risk assessment is not required.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = 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 for all commodities.

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 assumed 100 PCT and tolerance level residues for all 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Food Quality Protection Act (FQPA) Index Reservoir Screening Tool (FIRST) and a Provisional Cranberry Model for fenpyroximate and its metabolites (M1 and M3) in surface water and with Screening Concentration in Ground Water (SCI-GROW) for ground water, the estimated drinking water concentrations (EDWCs) of fenpyroximate for acute exposures are estimated to be 43 parts per billion (ppb) for surface water and 0.27 ppb for ground water, and for chronic exposures 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 and for the 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 FFDCFA 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 FFDCFA 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 Food Quality Protection Act Safety Factor (FQPA SF). In

applying this provision, EPA either retains the default value of 10X, or uses a different additional SF 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 prenatal and postnatal toxicity to fenpyroximate is low because:

- i. There was a clear NOAEL in the rat prenatal developmental toxicity study;
- ii. 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;
- iii. In the rabbit, there were no developmental effects reported at the levels tested; and
- iv. In the rat 2-generation reproductive toxicity study, there was no indication of increased prenatal or postnatal 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. 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 utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study. Increased (qualitative) prenatal susceptibility was seen following oral exposures in the rat developmental toxicity study, but the concern for these effects is low, for the reasons noted in Unit III.D.2. Therefore, a 10x FQPA SF is not necessary to account for this increased susceptibility of infants and children.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenpyroximate in drinking water. 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 14% of the aPAD for females 13-49 years old and 6.4% of the aPAD for children 1-2 years old, the population groups with the greatest risk estimate.

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 16% of the cPAD for children 1-2 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- and 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, chemical name 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 FFDC 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.

The Codex has established MRLs for fenpyroximate in or on citrus fruits at 0.5 ppm. This MRLs is different than the tolerance being established for fenpyroximate in the United States, however, harmonization with the Codex MRL is not possible because the U.S. tolerance expression includes an additional isomer and the U.S. use pattern requires a higher numerical value.

### *C. Revisions to Petitioned-For Tolerances*

Based on the Organization for Economic Co-operation and Development (OECD) tolerance-calculation procedure, the Agency is increasing the tolerance on citrus oil to 15 ppm rather than 14 ppm as proposed by the registrant.

## **V. Conclusion**

Therefore, existing tolerances for residues of fenpyroximate are increased in or on citrus, dried pulp from 2.5 ppm to 4.0 ppm; citrus, oil from 10 ppm to 15 ppm; and fruit, citrus, group 10-10 from 0.50 ppm to 1.0 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject

to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition,

this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 22, 2017.

Michael L. Goodis,

*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 the entries for “Citrus, dried pulp”, “Citrus, oil”, and “Fruit, citrus, group 10-10” in the table in paragraph (a)(1) to read as follows:

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

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

Commodity	Parts per million
*****	***
Citrus, dried pulp	4.0
Citrus, oil	15
*****	***
Fruit, citrus, group 10-10	1.0
*****	***

\* \* \* \* \*

[FR Doc. 2017-15728 Filed: 7/26/2017 8:45 am; Publication Date: 7/27/2017]