

*Populations* (59 FR 7629, February 16, 1994). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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) (Public Law 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).

VIII. 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: July 21, 2009. **G. Jeffrey Herndon,** 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 § 180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:  
**§ 180.910 Inert ingredients used pre-harvest and post-harvest; exemptions from the requirement of a tolerance.**  
\* \* \* \* \*

Inert Ingredients	Limits	Uses
* * *	* *	* *
Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10 or 30 moles (CAS Reg. No. 9014–85–1)	.....	Surfactants, related adjuvants of surfactants
* * *	* *	* *

- \* \* \* \* \*
- 3. In §180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:  
**§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.**  
\* \* \* \* \*

Inert Ingredients	Limits	Uses
* * *	* *	* *
Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10 or 30 moles (CAS Reg. No. 9014–85–1)	.....	Surfactants, related adjuvants of surfactants
* * *	* *	* *

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA–HQ–OPP–2008–0556; FRL–8420–6]**

**Fenpyroximate; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of

fenpyroximate in or on raw agricultural commodities (RAC): Vegetables, fruiting, group 8 at 0.20 ppm; okra at 0.20 ppm; melon subgroup 9A at 0.10 ppm; and cucumber at 0.10 ppm. 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 July 29, 2009. Objections and requests for hearings must be received on or before September 28, 2009, 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:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0556. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**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; e-mail address: [jackson.sidney@epa.gov](mailto: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).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any

questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### *B. How Can I Access Electronic Copies of this Document?*

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

###### *C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 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-2008-0556 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before September 28, 2009.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2008-0556, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made

for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

##### **II. Petition for Tolerance**

In the **Federal Register** of August 13, 2008 (73 FR 47186) (FRL-8375-8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7365) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition 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-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 in or on food commodities vegetables, fruiting, group 08 at 0.20 ppm; okra at 0.20 ppm; melon subgroup 09A at 0.03 ppm; and cucumber at 0.05 ppm. That notice referenced a summary of the petition prepared by Nichino America, Inc., of Wilmington, DE 19808, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of available field trial residue data supporting the petition, EPA determined that the proposed tolerance levels for certain crops should be revised as follows: Melon subgroup 9A increased from 0.03 ppm to 0.10 ppm and cucumber increased from 0.05 ppm to 0.10 ppm. The reasons for these changes are explained in Unit IV.D.

##### **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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the petitioned-for tolerances for combined residues of fenpyroximate and its Z-isomer in or on food commodities vegetables, fruiting, group 8 at 0.20 ppm; okra at 0.20 ppm; melon subgroup 9A at 0.10 ppm; and cucumber at 0.10 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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 has moderate oral and inhalation toxicity. It has low dermal toxicity and is not an eye or skin irritant. Fenpyroximate is a slight to moderate skin sensitizer by the maximization test method.

Subchronic oral toxicity studies in the rat show the primary effects included decreased body-weight and weight gain at the lowest observed adverse effect level (LOAEL) while there were hematological effects at higher doses. In the 21-day dermal toxicity study in rats, there were clinical signs in the females (including red nose/mouth/nasal discharge); decreased body-weights, body-weight gains, and food consumption in males and females; and increased liver weights and hepatocellular necrosis in the females. In the subchronic oral dog study, there was bradycardia observed at the LOAEL. This effect was present at 6 weeks (first time point measured) and did not appear to increase in severity with time. Also observed at this dose level were diarrhea, decreased body-weight, body-weight gain, and food consumption. At higher doses, there was also emesis. The highest dose resulted in first- and second-degree heart block, increased urea concentration, decreased glucose and altered plasma electrolyte levels among other signs of toxicity.

In the chronic oral rat and mouse studies, signs of toxicity were similar to

those in the oral subchronic rat study. The chronic dog study also revealed signs of toxicity including bradycardia, diarrhea, decreased body-weight gain, and food consumption.

The 2-generation reproductive toxicity study indicated that maternal (decreased body-weight) and offspring toxicity (decreased lactational weight gain) occurred at the same dose, suggesting no evidence of sensitivity or susceptibility. Reproductive parameters were not affected in this 2-generation reproduction study. The rat and rabbit developmental toxicity studies were tested at doses that produced minimal maternal toxicity.

There are no neurotoxicity studies other than a negative delayed acute neurotoxicity study in the hen. There was no indication of neurotoxicity present in any of the existing subchronic or chronic toxicity studies.

There was no concern for mutagenic activity in several studies including: *Salmonella*, *E. Coli*, *in vitro* mammalian cell gene mutation assay at the HGPRT locus, mammalian cell chromosome aberration assay, *in vivo* mouse bone marrow micronucleus assay, DNA repair disk diffusion assay, and an unscheduled DNA synthesis assay.

There was no evidence of carcinogenic potential in either the rat or mouse study.

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. Petition for the Establishment of Permanent Tolerances for Residues on Fruiting Vegetable (crop Group 8), Okra. Human Health Risk Assessment*, dated 12/23/2008, page 14 in docket ID number EPA-HQ-OPP-2008-0556-0004.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction

with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 can be found at <http://www.regulations.gov> in document *Fenpyroximate. Petition for the Establishment of Permanent Tolerances for Residues on Fruiting Vegetable (Crop Group 8), Okra. Human Health Risk Assessment*, dated 12/23/2008, page 12 in docket ID number EPA-HQ-OPP-2008-0556-0004.

#### 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. An acute dietary-exposure assessment was conducted for females 13–49 years old. Since an effect of concern attributable to a single dose in toxicity studies was not identified for the general U.S. population, an acute dietary-exposure assessment was not

performed for subgroups other than females 13–49 years old.

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 conducted acute dietary analysis for fenpyroximate assuming 100 percent crop treated (PCT) and existing and proposed tolerance-level residues for all commodities. DEEM (ver. 7.81) default processing factors were assumed 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); and peppermint and spearmint oil (0.08x). The petitioner submitted adequate tomato processing data indicating that residues of fenpyroximate *per se* did not concentrate in tomato paste or puree as all processing factors were <1.0x. Residues of the Z-isomer did not concentrate in tomato puree; however, residues of Z-isomer concentrated slightly in tomato paste. When residues are combined, the average processing factors were <0.89x for tomato paste and <0.57x for tomato puree. Default processing factor of 1.0x was assumed for both tomato paste and tomato puree. Available data support processing factors presented in Unit C.1. for stated 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 and existing and proposed tolerance-level residues for all commodities. DEEM (ver. 7.81) default processing factors were assumed with the exceptions listed in Unit C.1.

iii. *Cancer.* Fenpyroximate is classified as “not likely to be a human carcinogen.” There was no evidence of carcinogenicity in mice studies or in combined chronic/carcinogenicity studies in the rat. In addition, bacterial reverse mutation and *in vitro* mammalian cell gene mutation studies showed no mutagenic effects. Therefore, a cancer dietary exposure assessment was not performed.

The assumption of 100 PCT and tolerance level residues was made for all registered and proposed commodity uses of fenpyroximate.

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>.

The nature of fenpyroximate residues in plants and animals is understood. The residues of concern for plants are fenpyroximate and its Z-isomer (also referred to as M-1). The residues of concern for livestock milk, fat, meat and meat by-products are parent and multiple metabolites. Livestock residues, however, are not relevant to this petition. EPA determined that the residues in plants and livestock raw agricultural commodities for the purposes of tolerance enforcement and risk assessment are the parent compound, fenpyroximate, plus its Z-isomer and metabolites and that parent, Z-isomer and metabolite M-3 should be considered as residues of concern in drinking water. Based on the proposed application rates and the environmental fate properties of fenpyroximate, some surface and ground water contamination may occur. However, the risk of water contamination from parent compound is relatively low, based on its high sorption potential. Unlike parent compound, the sorption of the M-3 metabolite is much less, and it may move into water resources more readily. Environmental fate data indicate that parent and its Z-isomer are stable to photolysis in soil and immobile in soil. Major degradates formed in the aqueous layer were M-3 (50%), M-8 (36%), M-16 (4-hydroxymethylbenzoic acid, 58%) and M-11 (25 to 30%), and M-3 (>10%), M-11 (25 to 30%) and M8 (16 to 19%) in the soil. However, data from a field dissipation study showed M3 (32%) being the only significant degradate found in the field. Based on the structural similarity between parent and M-3, the Agency concluded that parent and M-3 should be included in the risk assessment.

The EDWCs were Tier 1 estimates for ground water using the Screening Concentration in Ground Water (SCI-GROW) model and surface water using the First Index Reservoir Screening Tool (FIRST) model for fenpyroximate and its metabolites. The models utilized an application rate of 0.2 lb ai/A with 2 applications per season.

Based on the FIRST, and SCI-GROW models, the EDWCs of fenpyroximate for acute exposures are estimated to be 8.74 parts per billion (ppb) for surface water and 0.001 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 0.51

ppb for surface water and 0.001 ppb for ground water. Parent, Z-isomer and metabolite M-3 are of concern in 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 8.74 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.51 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://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 are available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no concern for pre- and/or post-natal toxicity resulting from exposure to fenpyroximate. There is no evidence (qualitative or quantitative) of increased susceptibility following pre- and post-natal exposure in adequate developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat.

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 adequate to characterize potential pre-natal and post-natal risk for infants and children. Acceptable/guideline studies for developmental toxicity in rats and rabbits and reproduction toxicity in rats are available for FQPA assessment.

EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect relatively recently, these studies are not yet available for fenpyroximate. In the absence of specific immunotoxicity studies, EPA has evaluated the available fenpyroximate toxicity database to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. No evidence of immunotoxicity was found. Due to the lack of evidence of immunotoxicity for fenpyroximate, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL less than the crfD NOAEL of 0.97 mg/kg bw/day already established for fenpyroximate, and an additional factor (UF<sub>DB</sub>) for database uncertainties is not needed to account for potential immunotoxicity.

Acute and subchronic neurotoxicity testing in rats is also required as a result of changes made to the pesticide data requirements in December of 2007. Although neurotoxicity studies in rats have not yet been submitted, there is no evidence of neurotoxicity in any study in the toxicity database for fenpyroximate. Therefore, EPA has concluded that an additional uncertainty factor is not needed to account for the lack of these data.

The residue chemistry and environmental fate databases are 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 no 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.

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 for existing and proposed uses. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenpyroximate will occupy 6.6% of the aPAD for (females 13–49 years) the only population group of interest.

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 38% 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-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Fenpyroximate is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to fenpyroximate through food and water and will not be greater than the chronic aggregate risk.

#### *4. Intermediate-term risk.*

Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Fenpyroximate is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to fenpyroximate through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

#### *5. Aggregate cancer risk for U.S.*

*population.* Fenpyroximate is classified as not likely to be carcinogenic to humans. Therefore, fenpyroximate is not expected to pose a cancer risk.

6. *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*

An adequate enforcement method is available for determination of fenpyroximate residues of concern in plants. A gas chromatography method with nitrogen/phosphorus detection (GC/NPD), Method S19, has passed an Agency validation. Method S19 has a limit of quantitation of 0.10 ppm for the combined residues of fenpyroximate and its Z-isomer.

Adequate enforcement methodology (gas chromatography (GC/NPD)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

#### *B. International Residue Limits*

Codex and Mexican maximum residue limits (MRLs) are established for residues of fenpyroximate *per se* in/on several crop commodities but not for the crops requested. Harmonization with the other Codex and Mexican MRLs is not possible because the U.S. tolerance expressions include additional metabolites/isomers. There are currently no established Canadian MRLs.

### C. Revisions to Petitioned-For Tolerances

Based upon available data supporting petitioned-for tolerances, the Agency revised and/or modified the petitions as proposed in the notice of filing, as follows:

1. Proposed tolerance level for melon subgroup 9A at 0.03 ppm was increased to 0.10 ppm. Available residue data for cantaloupe, the representative crop, are adequate to fulfill data requirements. The number and locations of field trials conducted are in accordance with EPA Guideline 860.1500, and the trials reflect the proposed use pattern. The residue data were not entered into the Agency's tolerance spreadsheet because all treated samples bore combined residues below the limit of quantitation (LOQ) of <0.10 ppm. The available data for cantaloupe will support a tolerance of 0.10 ppm (the combined LOQs of the enforcement method for the parent compound and the Z-isomer) for fenpyroximate residues in/on melon subgroup 9A.

2. The Agency modified the proposed tolerance for residues in/on cucumber from 0.05 ppm to 0.10 ppm based on available residue data. Residue data include field trials where a single foliar application of fenpyroximate at maximum proposed seasonal rate was made. Results show that the maximum combined residues of fenpyroximate and its Z-isomer in/on cucumbers was <0.03 ppm at 7-day PHI.

These data were entered into the Agency's tolerance spreadsheet as specified by the Guidance for Setting Pesticide Tolerances Based on Field Trial Data SOP to determine an appropriate tolerance level. The Agency determined that the appropriate RAC tolerance for cucumber is 0.10 ppm (the combined LOQs of the enforcement method for the parent compound and the Z-isomer).

### V. Conclusion

Therefore, tolerances are established for combined residues 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 in or on food commodities: vegetables, fruiting, group 8 at 0.20 ppm; okra at 0.20 ppm; melon subgroup 9A at 0.10 ppm; and cucumber at 0.10 ppm.

### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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) (Public Law 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: July 20, 2009.

**G. Jeffrey Herndon,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

### PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

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

■ 2. Section 180.566 is amended by revising the term "residues" to read "combined residues" in introductory paragraphs (a)(1), (a)(2) and (a)(3); and by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

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

(a) *General.* (1) \* \* \*

Commodity	Parts per million
Cucumber .....	0.10
Melon subgroup 9A .....	0.10
Okra .....	0.20
Vegetable, fruiting, group 8 .....	0.20

\* \* \* \* \*

[FR Doc. E9-17942 Filed 7-28-09; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[EPA-HQ-OPP-2009-0189; FRL-8427-3]

**S-Absciscic Acid; Temporary Exemption From the Requirement of a Tolerance****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the biochemical pesticide *S*-Absciscic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2*Z*,4*E*)-dienoic Acid in or on leafy vegetables, herbs and spices, pome fruit, stone fruit, grapes and pineapples when applied/used as a plant regulator in accordance with the terms of Experimental Use Permit (EUP) 73049-EUP-7. Valent BioSciences Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *S*-Absciscic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2*Z*,4*E*)-dienoic Acid for the uses permitted under EUP 73049-EUP-7. The temporary tolerance exemption expires on August 7, 2012.

**DATES:** This regulation is effective July 29, 2009. Objections and requests for hearings must be received on or before September 28, 2009, 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:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0189. All documents in the docket are listed in the docket index

available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Chris Pfeifer, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0031; e-mail address: [pfeifer.chris@epa.gov](mailto:pfeifer.chris@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:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to

assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

**B. How Can I Access Electronic Copies of this Document?**

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s e-CFR site at <http://www.gpoaccess.gov/ecfr>.

**C. Can I File an Objection or Hearing Request?**

Under section 408(g) of FFDCA, 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. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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-2009-0189 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 28, 2009.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2009-0189, by one of the following methods.