

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: September 19, 2005

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 180.510 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.510 Pyriproxyfen; tolerances for residues.

(a) * * *

Commodity	Parts per million
Citrus hybrids	0.30
Grape	2.5
Grass, forage, fodder, and hay, group 17, forage	0.70
Grass, forage, fodder, and hay, group 17, hay	1.1
Onion, dry bulb	0.15
Strawberry	0.30
Vegetable, legume, group 6	0.20
White sapote	0.30

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2005-0133; FRL-7738-7]

Fenpropathrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenpropathrin in or on bushberry subgroup 13B; lingonberry; juneberry; salal; pea, succulent; and vegetable, fruiting, group 8. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 23, 2005. Objections and requests for hearings must be received on or before November 22, 2005.

ADDRESSES: To submit a written objection or hearing request follow the

detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP-2005-0133. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number:

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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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm/>.

II. Background and Statutory Findings

In the **Federal Register** of March 24, 2004 (69 FR 13833) (FRL-7347-2-), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions PP 1E6261, PP 1E6331, PP 1E6336, and PP 3E6588 by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The petitions requested that 40 CFR 180.466 be amended by establishing tolerances for residues of the insecticide fenprothrin, α -cyano-3-phenoxybenzyl 2,2,3,3-tetra-methylcyclopropanecarboxylate, in or on currant at 3.0 parts per million (ppm) requested by PP 1E6261; vegetable, fruiting, group 8, except tomato at 1.0

ppm requested by PP 1E6331; pea, succulent at 0.02 ppm requested by PP 1E6336, and bushberry subgroup 13B, lingonberry, juneberry, and salal at 3.0 ppm requested by PP 3E6588. Currant is a member of the bushberry subgroup, and will receive a tolerance at 3.0 ppm as requested for the bushberry subgroup. Therefore, a separate tolerance will not be established for currant under PP 1E6261. The proposed petition (1E6331) for vegetable, fruiting, group 8, except tomato at 1.0 ppm was subsequently amended to establish a tolerance for vegetable, fruiting, group 8 at 1.0 ppm. The Agency will delete the existing tolerance for tomato at 0.6 ppm since tomato is covered by the vegetable, fruiting group 8 tolerance promulgated under this ruling. That notice included a summary of the petition prepared by Valent U.S.A. Corporation, the registrant. One comment was received. EPA's response to this comment is discussed in Unit IV.C. below.

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...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of these actions. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for tolerances for residues of fenprothrin on vegetable, fruiting, group 8 at 1.0 ppm; pea, succulent at 0.02 ppm; and bushberry subgroup 13B, lingonberry, juneberry, and salal at 3.0 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances 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 nature of the toxic effects caused by fenprothrin is discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity--rodents (Rat)	NOAEL = 15 milligrams/kilogram/day (mg/kg/day) LOAEL = 30 mg/kg/day based on clinical signs of tremors, body weight reductions, decreased blood clotting time in females, and possibly increased alkaline phosphatase levels (both sexes)
870.3150	90-Day oral toxicity--nonrodents (Beagle dog)	NOAEL = < 6.2 mg/kg/day LOAEL = 6.2 mg/kg/day based on effects on the gastrointestinal system, tremors, and body weight changes
870.3200	21-Day dermal toxicity (NZW rabbit)	NOAEL = >3,000 mg/kg/day Only local irritation was seen. There were no systemic effects, thus the LOAEL was not determined

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal developmental--rodents (Fischer Rats)	Maternal NOAEL = 3 mg/kg/day The maternal NOAEL for the developmental rat study was 3.0 mg/kg/day based on decreased food consumption and body weight gains. However, these effects are not characteristic of an acute exposure and are not a suitable option for this exposure scenario. One of the factors to consider in selecting an acute dietary endpoint is when the toxic effects occur. For an acute effect, a relevant endpoint would occur as the result of a single dose. Since the neurotoxic signs observed in the dams of the developmental rat study were most severe within two hours after dosing, the clinical effects are resultant from a single dose, and are therefore appropriate endpoints for acute exposure scenarios. Maternal LOAEL = 6 mg/kg/day based on decreased food consumption and body weight gains. At 10 mg/kg/day, 6 dams died between days 7 and 13, and one dam was sacrificed moribund on day 8. The remaining 23 dams survived through the end of gestation. Also in the high dose group, many clinical signs were observed in the dams including ataxia, sensitivity to external stimuli, spastic jumping, and tremors. These signs were most severe 2 hours post-dosing and during the first days of dosing. Developmental NOAEL = 6 mg/kg/day Developmental LOAEL = 10 mg/kg/day based on increased incidence of asymmetrical ossification of sternabrae and incomplete ossification of the 5th and 6th sternabrae.
870.3700	Prenatal developmental--nonrodents (NZW rabbit)	Maternal NOAEL = 4 mg/kg/day Maternal LOAEL = 12 mg/kg/day based on flicking of the forepaws Developmental NOAEL = >36 mg/kg/day No dose related effects were seen, thus the LOAEL was not determined
870.3800	Reproduction and fertility effects (Sprague-Dawley rats)	Parental/Systemic NOAEL = M:3.0; F: 3.0 mg/kg/day LOAEL = M: 8.9; F: 10.1 mg/kg/day based on death and clinical signs of neurotoxicity in females. Offspring NOAEL = M:3.0; F:3.4 mg/kg/day LOAEL = M: 8.9; F: 10.1 mg/kg/day based on increased mortality and body tremors.
870.4100	Chronic toxicity (Beagle Dog)	NOAEL = 2.5 mg/kg/day LOAEL = 6.25 mg/kg/day based on tremors and ataxia in both sexes
870.4200	Carcinogenicity- CD-1 mice	NOAEL = Not established LOAEL = M: >56.0; F: >65.2 mg/kg/day There was an overall lack of toxic response. However an aborted mouse carcinogenicity study demonstrated that at a slightly higher maximum tolerated dose (MTD) of 1,000 ppm, the test article was lethal to 15% of the mice after only 13 weeks. Thus the maximum dose used in this completed study (600 ppm) was very close to the MTD. A repeat study is not justified. no evidence of carcinogenicity
870.4300	Carcinogenicity-rat	NOAEL = M:17.06; F: 7.23 mg/kg/day LOAEL = 19.45 mg/kg/day based on increase mortality and body tremors in the females no evidence of carcinogenicity
870.5100	Gene mutation Bacterial Reverse Mutation Test	Negative in <i>Salmonella typhimurium</i> TA 1535, TA1537, TA1538, TA98, and TA100 and <i>Escherichia coli</i> Wp2 <i>uvrA</i> up to the limit concentration with evidence of compound insolubility
870.5300	Gene Mutation <i>In vitro</i> mammalian cell gene mutation test	There was no clear evidence (or a concentration related positive response) of induced mutant colonies over background
870.5375	Cytogenetics <i>In vitro</i> mammalian cell chromosomal aberration assay	Negative in Chinese hamster ovary (CHO) cells (cytotoxicity observed at ≥ 30 $\mu\text{g/mL}$ -S9 and compound precipitation at 1,000 $\mu\text{g/mL}$ +S9)
870.5500	Other effects Bacterial DNA damage or repair test	Negative in <i>Bacillus subtilis</i> H17 (DNA repair proficient) and M45 (DNA repair deficient)
870.5900	Other effects <i>In vitro</i> sister chromatid exchange assay	Negative in CHO cells up to the solubility limit.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics (Sprague-Dawley rat)	Greater than 99% of the administered dose was excreted within 168 hours with 28% to 56% excreted in the urine and the remainder in the feces. Major biotransformations of the absorbed compound included the oxidation of the methyl group of the acid moiety, hydroxylation at the 4'-position of the alcohol moiety, cleavage of the ester linkage, and conjugation with sulfuric acid or glucuronic acid. Mean dermal absorption for the 10-hour interval was 33.3%, 20.1%, and 17.6% in the low, mid, and high dose groups, respectively
870.7600	Dermal penetration-rats	Dermal absorption increased with dose but not proportionally. The percentage of the dose absorbed decreased with the increasing administered dose. The total body burden could be expected to rapidly decrease due to excretion via urine and feces. Mean dermal absorption for the 10-hour interval was 33.3%, 20.1%, and 17.6% in the low, mid, and high dose groups, respectively

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL

was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount

of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/pesticides/health/human.htm>.

A summary of the toxicological endpoints for fenpropathrin used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FENPROPATHRIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population including infants and children)	NOAEL = 6 mg/kg/day UF = 1,000 Acute RfD = 0.006 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD ÷ Special FQPA SF = 0.006 mg/kg/day	Developmental Toxicity in Rats LOAEL = 10 mg/kg/day based on death and neurological signs At 10 mg/kg high dose death in 6 out of 30
Chronic Dietary (All populations)	NOAEL = 2.5 mg/kg/day UF = 1,000 Chronic RfD = 0.0025 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD ÷ Special FQPA SF = 0.0025 mg/kg/day	52-Week Chronic Oral Toxicity in Dogs LOAEL = 6.25 mg/kg/day based on tremors and ataxia in both sexes
Cancer (oral, dermal, inhalation)	Classification: Not likely to be carcinogen to humans		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.466) for the residues of fenpropathrin, in or on the following raw agricultural commodities: Cotton; grapes; strawberries; peanuts; tomatoes; Brassica, head and stem, Crop Subgroup 5A; fruit, citrus, group 10; fruit, pome, group 11; eggs; milk fat; and the meat; meat byproducts, and fat of cattle, goats, hogs, horses, sheep, and poultry. Risk assessments were conducted by EPA to assess dietary

exposures from fenpropathrin in food as follows

i. *Acute exposure.* Acute dietary 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. In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID, Version 2.03), which incorporates food consumption data as reported by respondents in the USDA 1994–1996

and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The acute dietary exposure analysis was a refined one. It was refined through the use of crop field trial data, Pesticide Data Program (PDP) monitoring data, anticipated residues (ARs) in animal commodities, processing factors, and percent crop treated and projected percent crop treated estimates.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation

Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure analysis was also a refined one. It was refined through the use of crop field trial data, PDP monitoring data, ARs in animal commodities, processing factors, and average percent crop treated and projected market share estimates.

iii. *Cancer.* A cancer dietary exposure analysis was not performed because fenpropathrin was classified as “not likely to be carcinogenic to humans.”

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of

the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used maximum PCT information as follows: Apples 15%; broccoli <2.5%; brussels sprouts <2.5%; cabbage <1%; cantaloupes 10%; cotton <2.5%; grapefruit 5%; grapes 10%; oranges 5%; peanuts <2.5%; pears 10%; pumpkins <2.5%; squash 10%; strawberries 20%; tangerines <2.5%; tomatoes <2.5%; and watermelons <2.5%; blueberries 18%.

The Agency used average PCT information as follows: Apples 10%; broccoli <1%; brussels sprouts <2.5%; cabbage <1%; cantaloupes 5%; cotton <1%; grapefruit 2%; grapes 5%; oranges 2%; peanuts <1%; pears 5%; pumpkins <1%; squash 5%; strawberries 15%; tangerines <1%; tomatoes <1%; and watermelons <1%; peas 27%; peppers 49%.

The Agency used projected acreage PCT information as follows: Blueberries 18%; peas 27%; peppers 49%.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available Federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. The percent of crop treated for grapefruit and oranges is 2%. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available Federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five. In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent 6 years.

EPA projects PCT for a new insecticide use by assuming that the PCT for the insecticide's initial 5 years will not exceed the average PCT of the dominant insecticide (the one with the largest PCT) within all insecticides over the three latest available years. The PCTs included in the average may be for the same insecticide or for different insecticides since the same or different insecticides may dominate for each year selected. Typically, EPA uses USDA/NASS as the source for raw PCT data

because it is non-proprietary and directly available without computation.

This method of projecting PCT for a new insecticide use, with or without regard to specific pest(s), produces an upper-end projection that is unlikely, in most cases, to be exceeded in actuality because the dominant insecticide is well-established and accepted by farmers. Factors that bear on whether a projection based on the dominant insecticide could be exceeded are whether the new insecticide is more efficacious or controls a broader spectrum of pests than the dominant insecticide, whether it is more cost-effective than the dominant insecticide, and whether it is likely to be readily accepted by growers and experts. EPA has considered these factors for the new uses of this insecticide, and indicates that it is unlikely that actual PCT for this new use will exceed the PCT for the dominant insecticide in the next 5 years.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fenpropathrin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of fenpropathrin. Further information regarding EPA drinking water models used in pesticide exposure assessments can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWC's) of fenpropathrin for acute exposures are estimated to be 10.3 parts per billion (ppb) for surface water and 0.005 ppb for ground water. The EDWC's for chronic exposures are estimated to be 1.8 ppb for surface water and 0.005 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID). For acute dietary risk assessment, the peak water concentration value of 10.3 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the annual average concentration of 1.8 ppb was used to access 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).

Fenpropathrin is not registered for use on any sites that would result in residential exposure.

4. Cumulative effects from substances with a common mechanism of toxicity.

Fenpropathrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids. Although all pyrethroids interact with sodium channels, there are multiple types of sodium channels, and it is currently unknown whether they have similar effects on all channels. In addition, EPA does not have a clear understanding of effects on key downstream neuronal function, e.g., nerve excitability, nor does EPA understand how these key events interact to produce their compound-specific patterns of neurotoxicity. There is ongoing research by both the EPA's Office of Research and Development and the pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. This research is expected to be completed by 2007. When the results of this research are available, the Agency will make a determination of common mechanism of toxicity as a basis for assessing cumulative risk. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value

based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. Prenatal and postnatal sensitivity.

The Agency has determined that there is no concern for pre- and/or post-natal toxicity resulting from exposure to fenpropathrin based on the submitted guidelines studies. There is no evidence (qualitative or quantitative) of increased susceptibility following *in utero* and/or pre- or post-natal exposure in adequate developmental toxicity studies in rats or rabbits and in a two-generation reproduction study in rats. In the rat developmental toxicity study, developmental effects occurred at a dose that was higher than the dose that caused maternal toxicity. In the study in rabbits, no developmental effects were seen at the highest dose tested. In the two-generation reproduction study in rats, the deaths in two pups of the F2 generation were not considered to be evidence of qualitative increased susceptibility as (i) the deaths occurred at the same dose that caused severe maternal toxicity (i.e., maternal deaths and neurotoxic clinical signs) and, (ii) the deaths occurred during lactation (days 19 and 21) when these pups were exposed to the compound via the milk and the diet. The Agency has concluded that there are no concerns or residual uncertainties for pre- and post-natal toxicity, based on the submitted guideline study results. However, EPA is lacking acute and subchronic neurotoxicity studies, and a developmental neurotoxicity study. The developmental neurotoxicity study has been required based on neurotoxicity being seen in all four tested animal species, and the fact that no detailed neuropathology data were available.

3. *Conclusion.* Because analysis of the existing database does not provide a reliable basis for concluding that these missing studies will not affect the regulatory endpoints for fenpropathrin, EPA is retaining the additional 10X FQPA factor for fenpropathrin, in the form of a database uncertainty factor, for the protection of infants and children.

E. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against EDWCs. The DWLOC values are not regulatory standards for drinking water, but are theoretical upper limits on a pesticide's concentration in drinking

water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter(L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EDWCs for surface water and ground water are less than the calculated DWLOCs, EPA can conclude with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposures for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. When new uses are added EPA reassesses the potential impacts of residues of the pesticide in drinking water as a part of the aggregate assessment process.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface and ground water EDWCs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure and drinking water, the acute dietary exposure from food and water to fenpropathrin will occupy 50% of the aPAD for the U.S. population, 43% of the aPAD for females 13 years

and older, 86% of the aPAD for all infants <1 year old, and 91% of the aPAD for children 3 to 5 years old, the subpopulation at greatest exposure. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure and drinking water, EPA has concluded that exposure to fenpropathrin from food and water will utilize 3.7% of the cPAD for the U.S. population, 6.7% of the cPAD for all infants < 1 year old, the subpopulation at greatest exposure, and 6.4% of the cPAD for children 1 to 2 years old. There are no residential uses for fenpropathrin. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fenpropathrin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risks are the sums of the risks from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* Fenpropathrin has been classified as not likely to be carcinogenic to humans. Therefore, fenpropathrin is expected to pose at most a negligible cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to fenpropathrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An enforcement method is available for the analysis of fenpropathrin in plants. This method, Residue Method Number RM-22-4 (11/1/89, revised 5/3/93) is entitled "Determination of Fenpropathrin in Crops." Residues in crops are extracted with acetone/hexane, partitioned into hexane, cleaned up by silica gel and C₁₈ Sep Pak chromatography, and measured by gas chromatography equipped with an electron capture detector. The limit of detection of this method is 0.01 ppm. An EPA trial of this method for the determination of fenpropathrin residues in apples has been successfully conducted. No additional animal commodity tolerances are being established with these petitions. As a

result, enforcement methods for animal commodities are not being addressed. Recovery of fenpropathrin was tested through FDA multiresidue methods, and fenpropathrin was found to be completely recovered by the PAM I Section 302 Method (Luke Method).

Adequate enforcement methodology 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.

B. International Residue Limits

There are no Codex, Canadian, or Mexican MRLs for fenpropathrin in or on the proposed commodities. Therefore, harmonization of tolerances is not an issue.

C. Response to Comments

One comment was received from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency has received this same comment from this commenter on numerous previous occasions and rejects it for the reasons previously stated (70 FR 1349, 1354, January 7, 2005).

V. Conclusion

Therefore, the tolerances are established for residues of fenpropathrin, α -cyano-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate, in or on bushberry subgroup 13B; lingonberry; juneberry, and salal at 3.0 ppm; pea, succulent at 0.02 ppm, and vegetable, fruiting, group 8 at 1.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, 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. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and

409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2005-0133 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 November 22, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2005-0133, to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a

copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to petitions 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety*

Risks (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and

responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: September 19, 2005.

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 180.466 is amended in the table to paragraph (a) by removing the commodity "tomato" and by adding alphabetically commodities to the table to read as follows:

§ 180.466 Fenpropathrin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Bushberry subgroup 13B	3.0
Juneberry	3.0
Lingonberry	3.0

Commodity	Parts per million
* * * *	*
Pea, succulent	0.02
* * * *	*
Salal	3.0
* * * *	*
Vegetable, fruiting, group 8	1.0

[FR Doc. 05-19062 Filed 9-22-05; 8:45 am]
 BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2005-0017; FRL-7736-4]

Kasugamycin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of kasugamycin in or on fruiting vegetables, crop group 8. Arysta Lifescience North American Corporation (previously known as Arvesta Corporation), agent for Hokko Chemical Industry Corporation, requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 23, 2005. Objections and requests for hearings must be received on or before November 22, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the

SUPPLEMENTARY INFORMATION. EPA has established a docket for this action under Docket identification (ID) number OPP-2005-0017. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall#2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9354; e-mail address: waller.mary@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgrstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly

to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm/>.

II. Background and Statutory Findings

In the **Federal Register** of April 8, 2005 (70 FR 17997) (FRL-7704-2), 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 3E6579) by Arysta Lifescience North American Corporation, 100 First Street, Ste. 1700; San Francisco, CA 94105; agent for Hokko Chemical Industry Corporation Ltd., 4-20, Nihonbashi Hongochkucho 4 Chome, Chuo-Ku, Tokyo 103-8341, Japan. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide kasugamycin, 1L-1,3,4/2,5,6-1-deoxy-2,3,4,5,6-pentahydroxycyclohexyl-2-amino-2,3,4,6-tetrahydroxy-4-([α]-iminoglycino)-[α]-D-arabino-hexapyranoside, in or on fruiting vegetables (Crop Group 8) at 0.04 parts per million (ppm), tomato juice at 0.06 ppm, tomato puree at 0.06 ppm, and tomato paste at 0.25 ppm. That notice included a summary of the petition prepared by Arysta Life Science North American Corporation, agent for Hokko Chemical Industry Corporation, LLC, the registrant. Comments were received on the notice of filing. EPA’s response to these comments is discussed in Unit IV.C. below.

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. . . .”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see <http://>