DELEGATION STATUS FOR PART 63 STANDARDS—ARIZONA

Subpart	Description	ADEQ [1]	MCESD [2]	PDEQ [3]	PCAQCD [4]
A	General Provisions	X	X	X	X
F	Synthetic Organic Chemical Manufacturing Industry	X	X	X	X
G	Synthetic Organic Chemical Manufacturing Industry: Process Vents, Storage Vessels, Transfer Operations, and Wastewater.	X	X	X	X
H	Organic Hazardous Air Pollutants: Equipment Leaks	X	X	X	X
I	Organic Hazardous Air Pollutants: Certain Processes Subject to the Negotiated Regulation for Equipment Leaks.	X	X	X	X
L	Coke Oven Batteries	X	X	X	X
M	Perchloroethylene Dry Cleaning	X	X	X	X
N	Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks	X	X	X	X
O	Ethylene Oxide Sterilization Facilities	X	X	X	X
Q	Industrial Process Cooling Towers	X	X	X	X
R	Gasoline Distribution Facilities	X	X	X	X
S	Pulp and Paper Industry	X	.....	.....	.....
T	Halogenated Solvent Cleaning	X	X	X	X
U	Group I Polymers and Resins	X	X	.....	X
W	Epoxy Resins Production and Non-Nylon Polyamides Production	X	X	X	X
X	Secondary Lead Smelting	X	X	X	X
CC	Petroleum Refineries	X	X	X	X
DD	Off-Site Waste and Recovery Operations	X	X	.....	X
EE	Magnetic Tape Manufacturing Operations	X	X	X	X
GG	Aerospace Manufacturing and Rework Facilities	X	X	X	X
JJ	Wood Furniture Manufacturing Operations	X	X	X	X
KK	Printing and Publishing Industry	X	X	X	X
LL	Primary Aluminum Reduction Plants	X	.....	.....	.....
OO	Tanks—Level 1	X	X	.....	X
PP	Containers	X	X	.....	X
QQ	Surface Impoundments	X	X	.....	X
RR	Individual Drain Systems	X	X	.....	X
VV	Oil-Water Separators and Organic-Water Separators	X	X	.....	X
EEE	Hazardous Waste Combustors	X	.....	.....	.....
JJJ	Group IV Polymers and Resins	X	X	.....	X

[1] Arizona Department of Environmental Quality.
[2] Maricopa County Environmental Services Department.
[3] Pima County Department of Environmental Quality.
[4] Pinal County Air Quality Control District.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300981; FRL–6492–6]

RIN 2070–AB78

Fenpropathrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenpropathrin (alpha-cyano-3-phenoxy-benzyl 2,2,3,3-tetra-methylcyclopropanecarboxylate) in or on citrus, grapes, head and stem *Brassica* (crop subgroup 5A), melon (crop subgroup 9A) and pome fruits. Valent USA Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective March 2, 2000. Objections and requests for hearings, identified by docket control number OPP–300981, must be received by EPA on or before May 1, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300981 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: William Sproat, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8587; and e-mail address: sproat.william@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300981. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 5, 1998 (63 FR 41835) (FRL–6017–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions (PP 7F3485, 6F4648, 1F3949) for a tolerance by Valent USA Company, 1333 North California Boulevard, Suite 600, Walnut Creek, CA 94596–8025. This notice included a summary of the petition prepared by Valent USA Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.466 be amended by establishing a tolerance for residues of the insecticide fenpropathrin, in or on various food commodities as follows: (1) PP7F3485 proposes the establishment of tolerances for the pome fruit crop group (crop group 11) at 5.0 parts per million (ppm); (2) PP1F3949 proposes the establishment of tolerances for grapes at 5.0 ppm and the processed product raisins at 10 ppm; for the citrus fruit crop group (crop group 10) at 2.0 ppm and the processed product citrus oil at 50.0 ppm and dried citrus pulp at 4.0 ppm. Based on EPA's review of processing studies submitted by Valent, the petition was revised by the petitioner to propose the tolerance on citrus oil at 75.0 ppm; (3) PP6F4648 proposes the establishment of tolerances for the head and stem Brassica crop group (crop group 5A) at 3.0 ppm and the melons crop group (crop group 9A) at 0.5 ppm.

Fenpropathrin is the active ingredient in DANITOL 2.4 EC Spray (EPA Reg. No. 59639–35) and TAME 2.4 EC Spray (EPA Reg. No. 59639–77). Tolerances have been established on cottonseed; cottonseed oil; meat, meat byproducts, and fat of cattle, goats, hogs, horses, sheep and poultry; eggs; milkfat; peanuts; peanut hay; strawberries; and tomatoes. Fenpropathrin is currently proposed for use on pome fruits (crop group 11) including apples to control spotted tentiform leafminer, white apple leafhopper, tarnished plant bug, rosy apple aphid, potato leafhopper, apple maggot, codling moth, European apple sawfly, green fruitworm, lesser appleworm, Pandemis leafroller, plum curculio, obliquebanded leafroller, oriental fruitmoth, redbanded leafroller, spirea aphid, tufted apple budmoth, variegated leafroller, Japanese beetle, European red mite, twospotted spider mite, and pears to control pear psylla (overwintering adults) and codling moth; grapes to control eastern grape leafhopper, western grape leafhopper, variegated grape leafhopper, grape leaf skeletonizer, grape berry moth, and Japanese beetles; head and stem Brassica (crop group 5A) including cabbage, broccoli, Brussels sprouts, and cauliflower to control yellowstriped armyworms, cabbage looper, imported cabbageworm, silverleaf whitefly, sweetpotato whitefly, diamondback moth southern cabbageworm, cabbage webworm, green peach aphid, and cabbage aphid; citrus fruits (crop group 10) to control citrus thrips, citrus blackfly, citrus flat mite, citrus red mite, citrus rust mite, Texas citrus mite, and twospotted spider mite; and melons (crop group 9A) including watermelons, honeydews, and muskmelons to control fall armyworms, twospotted spider mite (except in CA), silverleaf whitefly and sweetpotato whitefly.

Section 408(b)(2)(A)(i) of the 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) 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) 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 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of fenpropathrin on pome fruit (crop group 11) and grapes at 5.0 ppm; head and stem Brassica (crop group 5A) at 3.0 ppm; citrus fruit (crop group 10) at 2.0 ppm; melons (crop group 9A) at 0.5 ppm; and in the processed products citrus oil at 75 ppm, raisins at 10 ppm, and dried citrus pulp at 4.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance 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 fenpropathrin are discussed in this unit.

1. Acute toxicity studies with technical fenpropathrin. Oral LD_{50} in the rat is 54.0 milligram/kilogram (mg/kg) for males and 48.5 (mg/kg) for females—Toxicity Category I; dermal LD_{50} is 1,600 mg/kg for males and 870 mg/kg for females—Category II; acute inhalation (unable to generate sufficient test article vapor or aerosol to elicit toxicity)—Category IV; primary eye irritation (no corneal involvement, mild iris and conjunctival irritation)—Category III; and primary dermal irritation (no irritation)—Category IV. Fenpropathrin is not a sensitizer.

2. In a subchronic oral toxicity study, rats were dosed at concentrations of 0, 3, 30, 100, 300, or 600 ppm in the diet. The lowest effect level (LEL) is 600 ppm (30 mg/kg/day) based on body weight reduction (female), body tremors, and increased brain (female) and kidney (male) weights. The no observed adverse effect level (NOAEL) is 300 ppm (15 mg/kg/day).

3. In a subchronic oral toxicity study, dogs were dosed at concentrations of 0, 250, 500, or 1,000 ppm in the diet. A 1,000 ppm dog was sacrificed moribund during the third week after having tremors and showing other signs of poisoning caused by the test article. Because of this death, the dose for this group was reduced to 750 ppm for the remainder of the study. The lowest observed adverse effect level (LOAEL) is 250 ppm (7.25 mg/kg/day) based on signs of GI tract disturbance. There was no NOAEL—note dog chronic, below).

4. In a 21-day dermal toxicity study, rabbits were dosed 5 days/week for 3 weeks on abraded or unabraded skin at doses of 0, 500, 1,200, or 3,000 mg/kg/day. There were no dose-related effects on body weight, food consumption, clinical pathology, gross pathology, or organ weights. Trace or mild inflammatory cell infiltration was seen in the intact and abraded skin in all groups, including controls, and was attributed to the test article. The systemic NOAEL is > 3,000 mg/kg/day. Local irritation only. Although a 21-day dermal toxicity study in rabbits is available, the Agency has determined that rats are the most sensitive species to ascertain the dermal toxicity potential of pyrethroid insecticides. Although these data are lacking, EPA has sufficient toxicity data to support these tolerances and these additional studies are not expected to significantly change the risk assessment.

5. In a 1-year feeding study, dogs were dosed at 0, 100, 250, or 750 ppm in the diet. The systemic LEL is 250 ppm (6.25 mg/kg/day) based on tremors in all dogs. The neurologic NOAEL is 100 ppm (2.5 mg/kg/day); the systemic NOAEL is 100 ppm (2.5 mg/kg/day).

6. In a chronic feeding/carcinogenicity study, rats were dosed at 0, 50, 150, 450, or 600 ppm in the diet (0, 1.93, 5.71, 17.06, or 22.80 mg/kg/day in males, and 0, 2.43, 7.23, 19.45, or 23.98 mg/kg/day in females). There was no evidence of carcinogenicity at any dose up to and including 600 ppm. The systemic NOAEL (male) is 450 ppm (17.06 mg/kg/day). The systemic NOAEL (female) is 150 ppm (7.23 mg/kg/day). Systemic LEL (male) is 600 ppm highest dose tested (HDT) based on increased mortality, body tremors, increased pituitary, kidney, and adrenal weights. The systemic LEL (female) is 450 ppm (19.45 mg/kg/day) based on increased mortality and body tremors.

7. In a chronic feeding/carcinogenicity study, mice were dosed at 0, 40, 150, or 600 ppm in the feed (0, 3.9, 13.7, or 56.0 mg/kg/day in males, and 0, 4.2, 16.2, or 65.2 mg/kg/day in females). Mortality was highest during the final quarter of the study, but the incidence was similar in all dosed and control groups. No other indications of toxicity or carcinogenicity were seen. The systemic NOAEL is > 600 ppm (HDT; male/female, 56.0/65.2 mg/kg/day).

8. In a developmental toxicity study in rats, pregnant female rats were dosed by gavage on gestation days 6–15 at 0 (corn oil control), 0.4, 1.5, 2.0, 3.0, 6.0, or 10.0 mg/kg/day. The maternal NOAEL is 6 mg/kg/day; maternal LEL is 10 mg/kg/day based on death, moribundity, ataxia, sensitivity to external stimuli, spastic jumping, tremors, prostration, convulsions, hunched posture, squinted eyes, chromodacryorrhea, and lacrimation; developmental NOAEL is 10 mg/kg/day.

9. In a developmental toxicity study in rabbits, pregnant female New Zealand rabbits were dosed by gavage on gestation days 7 through 19 at 0, 4, 12, or 36 mg/kg/day. Maternal NOAEL is 4 mg/kg/day; maternal LEL is 12 mg/kg/day based on grooming, anorexia, flicking of the forepaws; developmental NOAEL is > 36 mg/kg/day (HDT).

10. A 3-generation reproduction study was performed in rats. Rats were dosed with fenpropathrin at concentrations of 0, 40, 120, or 360 ppm (0, 3.0, 8.9, or 26.9 mg/kg/day in males; 0, 3.4, 10.1, or 32.0 mg/kg/day in females, respectively). Parents (male/female): Systemic NOAEL = 40 ppm (3.0/3.4 mg/kg/day). Systemic LEL = 120 ppm (8.9/10.1 mg/kg/day) based on body tremors with spasmodic muscle twitches, increased sensitivity and maternal lethality; reproductive NOAEL = 120 ppm (8.9/10.1 mg/kg/day). Reproductive LEL = 360 ppm (26.9/32.0 mg/kg/day) based on decrease mean F_{1B} pup weight, increased F_{2B} loss. Pups (male/female): Developmental NOAEL = 40 ppm (3.0/3.4 mg/kg/day). Developmental LEL = 120 ppm (8.9/10.1 mg/kg/day) based on body tremors, increased mortality.

11. Studies on gene mutation and other genotoxic effects: An Ames Assay was negative for *Salmonella* TA98, TA100, TA1535, TA1537, and TA1538; and *E. coli* WP2uvrA (trp-) with or without metabolic activation. Sister Chromosome Exchange in CHO–K1 Cells—there were no increases in sister chromatid exchanges seen in the CHO–K1 cells treated with S–33206 or the DMSO vehicle. Cytogenetics *in vitro* (CHO/CA)—negative for chromosome aberrations (CA) in Chinese hamster ovary (CHO) cells exposed *in vitro* to toxic doses (≧30 μg/mL) without activation; and to limit of solubility (1,000 μg/mL) with activation. In Vitro Assay in Mammalian Cells—equivocal results—of no concern. DNA Damage/Repair in *Bacillus subtilis*—not mutagenic or showing evidence of DNA damage at ≥5,000 μg/paper disk.

12. In a metabolism study in rats, animals were dosed with radiolabeled fenpropathrin radiolabeled in either the alcohol or acid portion of the molecule. Rats received 14 daily oral low-doses of 2.5 mg/kg/day of unlabeled fenpropathrin followed by a 15th dose of either the alcohol or acid radiolabeled fenpropathrin. Groups of rats received a single dose of either of the two radiolabeled test articles at 2.5 mg/kg or 25 mg/kg. No clinical signs were seen in any rats. The major biotransformations included oxidation at 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. Four metabolites were found in the urine of rats dosed with alcohol labeled fenpropathrin. The major metabolites were the sulfate conjugate of 3-(4'-hydroxyphenoxy)benzoic acid and 3-phenoxybenzoic acid (22–44% and 3–9% of the administered dose, respectively). The major urinary metabolites of the acid-labeled fenpropathrin were TMPA-glucuronic acid and TMPA–CH_2OH (11–26% and 6–10% of the administered dose, respectively). None of the parent chemical was found in urine. The major elimination products in the feces included the parent chemical (13–34% of the administered dose) and four metabolites. The fecal metabolites (and the percentage of administered dose) included CH_2OH-fenpropathrin (9–

20%), 4'-OH-fenpropathrin (4–11%), COOH-fenpropathrin (2–7%), and 4'-OH–CH_2OH-fenpropathrin (2–7%). There are no qualitatively unique plant metabolites. The primary aglycones are identical in both plants and animals; the only difference is in the nature of the conjugating moieties employed.

13. The metabolism and potential toxicity of the small amounts of terminal plant metabolites have been tested on mammals. Glucoside conjugates of 3-phenoxy-benzyl alcohol and 3-phenoxybenzoic acid, administered orally to rats, were absorbed as the corresponding aglycones following cleavage of the glycoside linkage in the gut. The free or reconjugated aglycones were rapidly and completely eliminated by normal metabolic pathways. The glucose conjugates of 3-phenoxybenzyl alcohol and 3-phenoxy-benzoic acid are less toxic to mice than the corresponding aglycones.

B. Toxicological Endpoints

1. *Acute toxicity.* An acute reference dose (RfD) of 0.06 mg/kg/day was established based on clinical signs of neurotoxicity on the day of dosing in dams during a developmental toxicity study in rats. The NOAEL was 6.0 mg/kg/day to which an uncertainty factor of 100 was applied.

2. *Short- and intermediate-term toxicity.* EPA did not select an end-point for short and intermediate dermal risk assessments based on the lack of dermal or systemic toxicity at 3,000 mg/kg/day in a 21-day dermal study in rabbits. Therefore, a dermal risk assessment is not necessary.

3.*Chronic toxicity.* EPA has established the RfD for fenpropathrin at 0.025 milligrams/kilograms/day (mg/kg/day). This RfD is based on the observance of tremors in dogs in the 1-year oral feeding study. The NOAEL was 2.5 mg/kg/day to which an uncertainty factor of 100 was applied.

4. *Carcinogenicity.* As no indication of carcinogenicity was seen in rats or mice, fenpropathrin was classified as a group E chemical. A cancer risk assessment is therefore not necessary.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.466) for the residues of fenpropathrin, in or on a variety of raw agricultural commodities. Tolerances are established on plant commodities ranging from 0.6 ppm on tomatoes to 20 ppm on peanut, hay. Tolerances are also established on animal commodities, including meat, milk, poultry, and eggs. Fenpropathrin is a pyrethroid insecticide with broad spectrum activity on insects and mites. When formulated as the product DANITOL 2.4 EC Spray, the product is registered for agricultural use on outdoor terrestrial food crops. A separate fenpropathrin product, TAME 2.4 EC Spray, is registered for commercial, professional non-food use on indoor and outdoor ornamental and nursery stock. There are no uses registered for professional indoor pest control, termite prevention, homeowner use, or turf application. Danitol 2.4 EC Spray contains 30.9% fenpropathrin by weight (2.4 pounds of fenpropathrin per gallon). Danitol 2.4 EC Spray is not to be applied through any type of irrigation system. Risk assessments were conducted by EPA to assess dietary exposures from fenpropathrin as follows:

i. *Acute exposure and risk.* 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. The Dietary Exposure Evaluation Model (DEEM) acute analysis provides an estimate of the distribution of single-day exposures for the overall U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the USDA 1989–1992 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity.

The percent acute population adjusted dose (aPAD) is a measure of how close the high end exposure comes to the aPAD. The percent aPAD that would be above EPA's level of concern is 100%. For this analysis the FQPA 10x safety factor was removed. As a result, the aPAD is equivalent to the acute RfD: 0.06 mg/kg/day. The exposure of all subgroups at the 99.9th percentile is below 100% aPAD with two exceptions: nursing infants and children 1–6 years (164% and 107%, respectively). In the analysis submitted by Valent all subgroups had exposures which were below 100% aPAD. However, Valent used the 1994–1996 food consumption survey. The Agency is in the process of reviewing the recipe translation for this survey. This review has not been completed. Therefore it is current EPA policy to use the 1989–1992 survey.

In the 1989–1992 survey there is a consumption value associated with grapes which can be considered to be aberrant. A single 10-month old nursing infant consumed ⅔ of a pound (310 grams) of grapes in 1-day. This is an unusually high quantity of grapes for an infant less than 1 years old to consume in 1-day. The percent aPAD for nursing infants at the 99.5th percentile of exposure is 92%. The exposure at the 99.5th percentile places less weight on the extreme value in the food consumption survey. There were only 4 nursing infants in the 1989–1992 survey who ate grapes. Because of the aberrant data point, the analysis was run using the 1994–1996 food consumption survey. When this survey is used the exposure of nursing infants at the 99.9th percentile of exposure is 50%. As for the subgroup children 1–6 years, EPA notes that at the 99.75th percentile of exposure (1989–1992 survey) the aPAD for this group decreases to 62%. In addition, when the analysis was run using the 1994–1996 food consumption database, the exposure of children 1–6 years decreased to 77% aPAD (99.9th percentile). The analysis was also run with grapes removed from the commodity residue list. The 1989–1992 food consumption survey was used. The most highly exposed subgroup is females (13+/nursing) which utilized 61% of the aPAD. This analysis confirms that in the 1989–1992 survey grapes is a major driver for acute dietary risk.

The acute analysis for fenpropathrin provides refined estimates (Tier 3) of dietary exposure for the U.S. population and all population subgroups. These estimates were made with the use of field trial values and percent crop treated (PCT) estimates. When the 1989–1992 food consumption survey is used, the U.S. population and most of the population subgroups are below EPA's level of concern. The population subgroups which are above EPA's level of concern are nursing infants and children 1–6 years. If the Agency uses data from the 1994–1996 food consumption survey for nursing infants and children 1–6 years, the exposure to these population subgroups is below EPA's level of concern. EPA feels that this action is justified for the following reasons: (1) There were only 4 nursing infants in the 1989–1992 survey who ate grapes (the one data point will therefore exert an inordinate amount of influence on the results of the analysis, particularly at the 99.9th percentile); (2) for most population subgroups the aPAD values given by the two consumption surveys were comparable; (3) field trial data were used in the analysis which makes the analysis more conservative than if monitoring data had been available; (4) although the analysis is refined there is still room for further refinement—100% PCT was assumed for the following crops: grapes, pome fruits, citrus, head and stem Brassica, and melons (based on PCT values for

registered uses, the PCT for proposed uses will probably be well below 100% once the uses are granted); and (5) although acute exposure to fenpropathrin resulting from residues present in animal commodities is refined, there is room for further refinement here also. Animal diets which are more realistic can be constructed. For this analysis the nutritional value of the diets has not been considered. Instead, maximum theoretical dietary burdens were constructed. EPA anticipates that the 1994–1996 food consumption survey will be available for use in the first quarter of calendar year 2000.

(ii). Chronic, non-carcinogenic dietary risk a DEEM chronic dietary exposure analysis was performed using anticipated residues (field trial data) and PCT data provided by the Agency. As with the acute analysis, EPA used the 1989–1992 food consumption data base whereas Valent used the 1994–1996 data base. The FQPA 10x safety factor was removed. As a result, the chronic PAD (cPAD) is equivalent to the chronic RfD: 0.025 mg/kg/day. Based on the 1989–1992 data base, the most highly exposed subgroup (children 1–6 years) utilized 9% of the cPAD. As a result, exposure to fenpropathrin of the U.S. population and all population subgroups is below EPA's level of concern.

Section 408(b)(2)(E) 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 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. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual PCT for assessing chronic dietary risk only if the Agency can make the following findings: 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; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and 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), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which may be applied in a particular area.

2. *From drinking water.* Fenpropathrin is persistent and immobile. There are no established Maximum Contaminant Levels for residues of fenpropathrin in drinking water. No health advisory levels for fenpropathrin in drinking water have been established (EPA Safe Drinking Water Hotline, 1(800)426–4791, date of call: September 7, 1999). EPA has used drinking water numbers based on Generic Estimated Environmental Concentration (GENEEC) and Screening Concentration in Ground Water (SCI–GROW) modeling.

The Agency used its SCI–GROW (Screening Concentration in Ground Water) screening model and environmental fate data to determine the estimated environmental concentration (EEC) for fenpropathrin in ground water. SCI–GROW is an empirical model based upon actual ground water monitoring data collected for the registration of a number of pesticides that serve as benchmarks for the model. The current version of SCI–GROW appears to provide realistic estimates of pesticide concentrations in shallow, highly vulnerable ground water sites (i.e., sites with sandy soils and depth-to-ground water of 10 to 20 feet). EPA reported a ground water EEC of 0.006 ppb for fenpropathrin applied to pears and citrus fruits.

The Agency used its GENEEC screening model and environmental fate data to determine the EECs for fenpropathrin in surface water. GENEEC is used to estimate pesticide concentrations in surface water for up to 56 days after a single runoff event. GENEEC simulates a 1 hectare by 2 meters deep edge-of-the-field farm pond which receives pesticide runoff from a treated 10 hectare field. GENEEC provides an upper-bound concentration value. GENEEC can substantially overestimate (by a ≥3-fold factor) true pesticide concentrations in drinking water. The acute (peak) value for use of fenpropathrin on pears and citrus fruits at the maximum application rate is 2.72 ppb and the chronic (average 56-day) value is 0.34 ppb.

A Drinking Water Level of Comparison (DWLOC) is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Different populations will have different DWLOCs. The Agency uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. They do have an indirect regulatory impact through aggregate exposure and risk assessments.

i. *Acute exposure and risk.* For purposes of this acute risk assessment, the estimated acute maximum concentration (EEC) for fenpropathrin in surface and ground waters (2.72 ppb) was used for comparison to the back-calculated DWLOCs for the acute endpoint. The drinking water EEC (when determined using dietary

exposures at the 99.9th percentile of exposure) exceeds the DWLOCs for the population subgroups nursing infants and children 1–6 years. The DWLOCs, which were calculated based on the exposure values at the 99.5th percentile of exposure for nursing infants and at the 99.75th percentile of exposure for children 1–6 years, were above the drinking water EEC. The same is true for the DWLOCs calculated based on the 99.9th percentile exposure values from the 1994–1996 food consumption survey. EPA anticipates that the 1994–1996 food consumption survey will be available for use in the first quarter of calendar year 2000. For this risk assessment only, the Agency is using the data from the 1994–1996 food consumption survey for these two population subgroups. Although the dietary exposure estimates are highly refined, EPA notes that 100% crop treated was used for the following crops: grapes, pome fruits, melons, citrus, and head and stem Brassica. Based on PCT values for registered uses, the PCT for proposed uses will probably be significantly less than 100%.

The DWLOCs were calculated based on the dietary analysis in which grapes were eliminated. Based on this analysis, for all population subgroups the acute DWLOCs exceed the drinking water EEC. For the population subgroup nursing infants and children 1–6 years, the DWLOC's were 400 and 250 ppb, respectively. Therefore, the acute risk of exposure to fenpropathrin from food and drinking water is below EPA's level of concern for the U.S. population and all population subgroups.

ii.*Chronic exposure and risk.* EPA generally reduces GENEEC model values by a factor of three when determining whether or not a chronic level of comparison has been exceeded. If the GENEEC model value is > 3 times the chronic DWLOC, the pesticide is considered to have passed the screen and no further assessment is needed. Acute DWLOCs are to be compared directly to GENEEC estimates; both acute and chronic DWLOCs are to be compared directly to SCI–GROW estimates. (Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments, December 2, 1997).

Based on the chronic dietary food exposure estimates, chronic DWLOCs for fenpropathrin were calculated. The lowest DWLOC is 230 ppb for nursing infants and children 1–6 years. The highest EEC for fenpropathrin in surface water is from the application of fenpropathrin to pears and citrus fruits (0.34 ppb) and is substantially lower than the DWLOCs calculated. Therefore, chronic exposure to fenpropathrin residues in drinking water do not exceed EPA's level of concern.

3. *From non-dietary exposure.* There are no current registered residential uses for fenpropathrin. However, the label for TAME 2.4 EC SprayTM does include nonfood use on indoor and outdoor ornamental and nursery plantings. According to the label, this product can be applied by Professional Certified Operators (PCO) only. Therefore, an assessment for residential handlers is not required.

There is potential for dermal and oral exposure to adults and children during postapplication activities. Because no dermal endpoint of concern was found in dermal studies, no risk from dermal exposure is expected. However, an exposure assessment was performed for the following postapplication exposure scenarios: (1) incidental non-dietary ingestion of pesticide residues on garden plants from hand-to-mouth transfer, and (2) incidental non-dietary ingestion of soil from pesticide-treated areas.

i. *Acute exposure and risk.* Using EPA Standard Operating Procedures for Residential Exposure Assessments (Draft, December 18, 1997), the Short-Term Exposure Estimates and Risk Assessment (day ''0'', postapplication must be assessed on the same day the pesticide is applied because it is assumed that toddlers could play in the ornamental site or garden immediately after application) were calculated. The MOE's for hand to mouth and soil ingestion are 120 and 460,000 respectively. These short term MOEs are above 100 and do not exceed EPA's level of concern.

The exposure estimates that were generated are based on some upper-percentile (i.e., maximum application rate, available residues, duration of exposure) and some central tendency (i.e., transfer coefficient, surface area, hand-to-mouth activity, and body weight) assumptions and are considered to be representative of high-end exposures. The uncertainties associated with this assessment stem from the use of an assumed amount of pesticide available from ornamentals, and assumptions regarding dissipation, transfer of chemical residues, and hand-to mouth activity. The estimated exposures are believed to be reasonable high-end estimates based on observations from chemical-specific field studies and professional judgement.

ii. *Chronic exposure and risk.* Intermediate-term and chronic postapplication exposures are not expected because these activities (incidental non-dietary ingestion of pesticide residues on garden plants from hand-to-mouth transfer and incidental non-dietary ingestion of soil from pesticide-treated areas) will not occur everyday at ornamental and nursery sites.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether fenpropathrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, fenpropathrin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fenpropathrin has 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 the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* For this risk assessment, the acute aggregate risk is equivalent to the risk from food + water. Using the 1994–96 Food Consumption Survey, it is estimated that acute exposure to fenpropathrin from food for the most highly exposed population subgroup, children (1–6 years), will utilize 77% of the acute PAD (see discussion in Unit III.C.). An acute dietary exposure (food + water) of 100% or less of the acute PAD is needed to protect the safety of all population subgroups. The EEC's of fenpropathrin in surface and ground water for acute exposure are below the DWLOCs. Thus, the acute aggregate risk of exposure to fenpropathrin from food and drinking water is below EPA's level of concern for the U.S. population and all population subgroups

2. *Chronic risk.* For this risk assessment, the chronic aggregate risk is equivalent to the risk from food + water. This is because there is no chronic residential exposure scenario. In

addition, no chronic dermal or inhalation endpoints were identified. As discussed above, EPA has concluded that exposure to fenpropathrin from food for the most highly exposed subgroup (children 1–6 years) will utilize 9% of the cPAD. EPA generally has no concern for exposure below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The EEC's for fenpropathrin in drinking water are substantially lower than the DWLOCs. Therefore, chronic aggregate risk does not exceed EPA's level of concern.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. A short-term aggregate risk assessment was performed for infants and children because of the existence of short-term postapplication residential exposure scenarios. There is a hand-to-mouth exposure of 0.049 mg/kg/day and a soil ingestion exposure of 0.000013 mg/kg/day. These exposures were aggregated with the average food exposure to arrive at short-term aggregate DWLOCs. These DWLOCs were then compared with the 56-day GENEEC maximum EEC of 0.34 ppb. For all infant/children population subgroups the DWLOCs exceeded the maximum EEC. As a result, the short-term aggregate risk from exposure to fenpropathrin does not exceed EPA's level of concern for any of the infant/children population subgroups. Intermediate-term endpoints were not identified. In addition, intermediate-term postapplication exposures are not expected from the registered residential use of fenpropathrin.

4. *Aggregate cancer risk for U.S. population.* The Agency has determined that there is no evidence of carcinogenicity in studies in either the mouse or rat.

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

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children—* i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of fenpropathrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 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 data base unless EPA determines 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* See Toxicological Profile in Unit III.A. of this preamble.

iii. *Reproductive toxicity study.* See Toxicological Profile in Unit III.A. of this preamble.

iv. *Prenatal and postnatal sensitivity.* There is no evidence of sensitivity to young rats or rabbits following prenatal or postnatal exposure to fenpropathrin.

v. *Conclusion.* There is a complete toxicity data base for fenpropathrin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the above, EPA concludes that reliable data support use of the 100-fold uncertainty factor and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* (Food + Water) The percentages of the acute PAD utilized at the 99.9 percentile exposure are 56% for infants and 77% for children (1–6 years), the most highly exposed population subgroup. The EEC for fenpropathrin in drinking water is below the DWLOC. The Agency has no cause for concern if total acute exposure is 100% or less of the acute PAD. Therefore, the Agency has no acute aggregate concern due to exposure to fenpropathrin through food and drinking water.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to fenpropathrin from food will utilize 5% of the cPAD for infants and 9% for children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to fenpropathrin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk.* See Aggregate Risks and Determination of Safety for US Population in Unit III (D)(3) above.

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

IV. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in plants is adequately understood. Adequate metabolism studies with three dissimilar crops have been submitted. The metabolism of fenpropathrin in apples, tomatoes, and cotton has been reviewed and has been considered adequate. The residue of concern is the parent compound fenpropathrin.

The nature of the residue in animals is adequately understood. Metabolism studies with goats and poultry dosed with radiolabeled fenpropathrin were submitted. The majority of the residue in muscle, fat, and milk and eggs was found to be the parent compound, fenpropathrin. The residue in kidney and liver consisted mainly of various metabolites. Livestock metabolites, with the possible exception of TMPA lactone, have also been identified in rat metabolism studies and their contributions to the overall toxicity of fenpropathrin have been considered. For the apple and pear tolerances, the levels of the metabolites in livestock were low enough not to be included in the tolerance expression. The organs in which metabolites of the synthetic pyrethroids are found (i.e., liver and kidney) are minor human food consumption items. As a result, the nature of the residue in animals is adequately understood for the purposes of this tolerance petition. The residue of

concern in livestock commodities is the parent compound.

B. Analytical Enforcement Methodology

EPA has concluded that adequate methodology is available for enforcement of the proposed tolerances for plant and animal commodities. Method RM–22–4 can be used for the analysis of fenpropathrin in citrus, grapes, head and stem Brassica crops, melons, and pome fruits. This method includes cleanup procedures for oily crops and oils. Residues are extracted with acetone/hexane, cleaned up with silica gel and C18 Sep Pak chromatography and detection is by gas chromatography. Oily crops are extracted with acetone/hexane, partitioned into hexane, cleaned up by gel permeation, silica gel, and C18 Sep Pak chromatography and detected by gas chromatography. Oils are partitioned between hexane and acetonitrile, cleaned up on an alumina column and determined by electron capture gas chromatography using a split/splitless capillary column. The limit of detection is reported as 0.01 ppm. An EPA trial of Method RM–22–4 to determine fenpropathrin residues in apples was successfully conducted. The method was also validated for meat and milk. 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).

C. Magnitude of Residues

An adequate number of residue field trials reflecting the proposed use rates were submitted to EPA to demonstrate that tolerances for pome fruit (crop group 11) and grapes at 5.0 ppm; head and stem Brassica (crop group 5A) at 3.0 ppm; citrus fruit (crop group 10) at 2.0 ppm; melons (crop group 9A) at 0.5 ppm; processed products citrus oil at 75 ppm, raisins at 10 ppm, and dried citrus pulp at 4.0 ppm will not be exceeded when fenpropathrin products labeled for these uses are used as directed.

D. International Residue Limits

There are Codex maximum residue levels MRLs of 5 ppm for both grapes and pome fruit. EPA is establishing tolerances of 5 ppm for these commodities which will result in harmonized tolerances.

E. Rotational Crop Restrictions

Rotational crop studies are not required for grapes, citrus, and pome fruit. The registrant submitted the results of confined and rotational crop studies. These studies are adequate to support the proposed use of fenpropathrin on head and stem Brassica and melons. No rotational crop restrictions or tolerances are required.

F. Endocrine Disruption

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. * * *'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for further endocrine disrupter effects.

V. Conclusion

Therefore, the tolerance is established for residues of fenpropathrin in pome fruit (crop group 11) and grapes at 5.0 ppm; head and stem Brassica (crop group 5A) at 3.0 ppm; citrus fruit (crop group 10) at 2.0 ppm; melons (crop group 9A) at 0.5 ppm; and in the processed products citrus oil at 75 ppm, raisins at 10 ppm, and dried citrus pulp at 4.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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 the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–300981 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 May 1, 2000.

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 issues(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 (1900), Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office

of Pesticide Programs, Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *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 Unit I.B.2. Mail your copies, identified by docket control number OPP–300981, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 file format 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

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: February 17, 2000.

James Jones,

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 § 180.466, by amending paragraph (a) by alphabetically adding the following entries to the table:

§ 180.466 Fenpropathrin; tolerances for residues.

(a) * * *

Commodity	Parts per million
Brassica, head and stem, crop subgroup 5–A	3.0
* * * * *	
Citrus, dried pulp	4.0
Citrus, oil	75

Commodity	Parts per million
* * * * *	
Fruits, citrus, crop group 10	2.0
Fruits, pome, crop group 11	5.0
* * * * *	
Grapes	5.0
* * * * *	
Raisins	10.0
* * * * *	
Vegetable, cucurbit, melon, crop subgroup 9–A	0.5

* * * * *

[FR Doc. 00–5046 Filed 3–1–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300980; FRL–6493–2]

RIN 2070–AB78

Imidacloprid; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety in or on corn, field fodder, forage, and grain. Gustafson, Incorporated requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996. The tolerance will expire on December 31, 2000.

DATES: This regulation is effective March 2, 2000. Objections and requests for hearings, identified by docket control number OPP–300980, must be received by EPA on or before May 1, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300980 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Peg Perreault, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5417; and e-mail address: Perreault.Peg@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and hen look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300980. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 25, 1997 (62 FR 34269) (FRL–5719–6), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA of 1996 (Public Law 104–170) announcing the filing of a pesticide petition (PP) for tolerance by Gustafson, Incorporated, P.O. Box 660065, Dallas, TX 75255–0065. This notice included a summary of the petition prepared by Gustafson, Incorporated, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.472(a) be amended by establishing tolerances for combined residues of the insecticide imidacloprid, (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine), in or on corn, field fodder at 0.2 parts per million (ppm), corn, field forage at 0.1 ppm, and corn, field grain at 0.05 ppm. The tolerances will expire on December 31, 2000. Time-limited tolerances are being established based on EPA's initial review of the crop field trial data for seed-treatment of field corn, which indicates that the data support the proposed tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety. The time-limited tolerances for field corn are being established until a full review of