

entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and

other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: February 24, 2009.

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 180.603 is amended by revising paragraph (b) to read as follows:

§ 180.603 Dinotefuran; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for combined residues of Dinotefuran, [*N*-methyl- *N'*-nitro- *N''*-(tetrahydro-3-furanyl)methyl]guanidine] and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Rice, grain	2.8	12/31/09

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0875; FRL-8400-8]

Fenpropathrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenpropathrin in or on almond, hulls at 4.5 parts per million (ppm); cherry, sweet, at 5.0 ppm; cherry, tart at 5.0 ppm; fruit, stone, crop group 12 (except cherry) at 1.4 ppm; nuts, tree, crop group 14 at 0.10 ppm; pistachio at 0.10 ppm, PP 4E6867; avocado at 1.0 ppm; black sapote at 1.0 ppm; canistel at 1.0 ppm; maney sapote at 1.0 ppm; mango at 1.0 ppm; papaya at 1.0 ppm; sapodilla at 1.0 ppm; star apple at 1.0 ppm, PP 6E7066; caneberry, subgroup 13-07A at 12 ppm; and olive at 5.0 ppm, PP 7E298. In addition, the Agency is deleting a time-limited tolerance on currant at 15 ppm which had an expiration date of 12/31/

2008. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 25, 2009. Objections and requests for hearings must be received on or before May 26, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0875. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m.

to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: jackson.sidney@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of

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

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

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

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0875 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before May 26, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2006-0875, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One

Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Petitioned for Tolerance

In the **Federal Register** of November 15, 2006, (71 FR 66520) (FRL-8102-5), and February 6, 2008 (73 FR 6964) (FRL-8350-9), 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 4E6867, 6E7066, and 7E7298) by IR-4, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petitions requested that 40 CFR 180.466 be amended by establishing tolerances for residues of the insecticide, fenprothrin, (alpha-cyano-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate), in or on fruit, stone, group 12 (except cherry) at 5.0 ppm; nut, tree, group 14 at 0.10 ppm, pistachio at 0.10 ppm, and almond hulls at 5.0 ppm, PP 4E6867; avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, star apple at 1.0 ppm; barley, grain at 0.30 ppm; barley, hay at 2.5 ppm; and barley, straw at 4.5 ppm, PP 6E7066; caneberry subgroup 13-07A at 12 ppm and olives at 5 ppm, PP 7E7298. That notice referenced a summary of the petition prepared by Valent, U.S.A., the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filings.

Based upon review of the data supporting the petitions listed in this Unit, EPA has made certain modifications including revisions to proposed tolerance levels, scope of proposed crop groups, existing tolerance levels, proposed commodity definitions, as follows: Changed the proposed tolerance for fruit, stone, group 12 to fruit, stone, group 12 (except cherry) and revised the tolerance level from 5.0 to 1.4 ppm; established an individual tolerance for cherry, sweet at 5.0 ppm, and cherry, tart at 5.0 ppm; changed the proposed tolerance for nut, tree, group 14 (including pistachio) to nut, tree, group 14; established an individual tolerance for pistachio at 0.10 ppm; revised the tolerance level for almond, hulls from 5.0 to 4.5 ppm, and corrected the commodity definition for caneberry, subgroup 13-07A. Additionally, at this time, the Agency is not making a

decision on the proposed tolerances for barley, grain at 0.30 ppm, barley, hay at 2.5 ppm, and barley, straw at 4.5 ppm pending submission and review of a barley processing study. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of, and to make a determination on, aggregate exposure for the petitioned-for tolerances for residues of fenprothrin in or on almond, hulls at 4.5 ppm; cherry, sweet at 5.0 ppm; cherry, tart at 5.0 ppm; fruit, stone, group 12 at 1.4 ppm; nut, tree, group 14 at 0.10 ppm; avocado at 1.0 ppm; black sapote at 1.0 ppm; canistel at 1.0 ppm; mamey sapote at 1.0 ppm; mango at 1.0 ppm; papaya at 1.0 ppm; sapodilla at 1.0 ppm; star apple at 1.0; caneberry, subgroup 13-07A at 12 ppm; olive at 5.0 ppm; and pistachio at 0.10 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

The database for fenprothrin is not complete, but it does provide adequate information to characterize toxicity. Acute neurotoxicity, subchronic neurotoxicity, and developmental neurotoxicity studies have been submitted and reviewed since the previous risk assessment. These studies were classified acceptable/guideline and

were considered during endpoint selection.

Fenpropathrin exhibits high toxicity through the oral and dermal routes of exposure. Acute inhalation toxicity has not been determined for fenpropathrin. Because of the chemical's low vapor pressure, sufficient test material could not be generated to elicit a toxic response during the inhalation studies. Fenpropathrin is a mild eye irritant, but does not cause dermal irritation in rabbits or skin sensitization in guinea pigs.

Clinical signs of toxicity observed in rats and dogs following subchronic exposure included tremors, ataxia, salivation, and hypersensitivity. Decreased body weights and food consumption are more general responses to dietary consumption in rats and dogs. Pregnant rabbits exposed to fenpropathrin during a developmental study also exhibited neurotoxic signs including tremors, shakiness, unsteadiness, and flicking limbs.

Chronic dietary exposure to fenpropathrin produced no treatment-related effects in mice. Following chronic exposure, rats and dogs showed evidence of neurotoxicity that was consistent with the effects that were seen after subchronic exposures. There was no evidence of carcinogenicity in either the rat or mouse long-term dietary studies. Fenpropathrin is not mutagenic in bacteria or cultured mammalian cells. This chemical is neither clastogenic nor damaging to DNA. Fenpropathrin is classified as "not likely to be carcinogenic to humans."

Developmental studies in rats and rabbits showed no evidence of increased susceptibility in fetuses as compared to maternal animals following exposure to fenpropathrin in utero. Maternal animals of both species exhibited clinical signs of neurotoxicity. In rats, reduced body weight gains were also present. In neither study did dose-related changes in fecundity, fertility, implantations, number of abortions, or early or late resorptions occur. The only anomaly noted for either species was an increased incidence of asymmetrical or incomplete ossification of the fifth or sixth sternbrae in rat fetuses. A two-generation reproduction study in rats, likewise, did not show an increased sensitivity to fenpropathrin in pups as compared to adults.

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable

subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by fenpropathrin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document "Fenpropathrin. Human health risk assessment for the proposed uses on barley, stone fruit (Crop Group 12), tree nuts (Crop Group 14), pistachio, caneberries (Crop Subgroup 13-07A), and star apple, dated 11/26/2008", page 13 in docket ID number EPA-HQ-OPP-2006-0875-0005.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment

process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for fenpropathrin used for human risk assessment can be found at <http://www.regulations.gov> in document "Fenpropathrin. Human health risk assessment for the proposed uses on barley, stone fruit (Crop Group 12), tree nuts (Crop Group 14), pistachio, caneberries (Crop Subgroup 13-07A), and star apple, dated 11/26/2008, page 19 in docket ID number EPA-HQ-OPP-2006-0875-0005.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenpropathrin, EPA considered exposure under the petitioned-for tolerances as well as all existing fenpropathrin tolerances in (40 CFR 180.466). EPA assessed dietary exposures from fenpropathrin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Acute dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID, Version 2.03), which uses food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). A partially refined acute probabilistic dietary exposure analysis was performed for fenpropathrin. As to residue levels in food, EPA's analysis was based on tolerance level residues for some commodities, crop field trial data (only for apricots, nectarines, apples, cherries, grapes, peaches, pears, and plums), processing factors, and the assumption of 100 percent crop treated for all registered and proposed commodity uses. As a result, the Agency considers these analyses to be refined, but not highly refined.

ii. *Chronic exposure.* Chronic dietary exposure assessments were conducted using the DEEM-FCID, (Version 2.03), which uses food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA's analysis was based on tolerance level residues for some commodities, crop field trial data (only for apricots, nectarines, apples, cherries, grapes, peaches, pears, and plums), processing factors, and the assumption of 100 percent crop treated for all registered and proposed commodity uses. As a

result, the Agency considers these analyses to be refined, but not highly refined.

iii. *Cancer.* An exposure assessment to evaluate cancer risk is unnecessary. There is no evidence of carcinogenicity in either the rat or mouse long-term dietary studies. Fenpropathrin is not mutagenic in bacteria or cultured mammalian cells. The chemical is neither clastogenic nor damaging to DNA. Fenpropathrin is classified as “not likely to be carcinogenic to humans.”

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCFA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCFA section 408(f)(1) 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. For the present action, EPA will issue such data call-ins as are required by FFDCFA section 408(b)(2)(E) and authorized under FFDCFA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCFA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: 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 the pesticide residue.

- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

- Condition c: 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 FFDCFA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

The assumption of 100% PCT was made for all registered and proposed commodity uses.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fenpropathrin in drinking water.

These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenpropathrin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) Model for surface water and Screening Concentration in Ground Water (SCI-GROW) Model for ground water, the estimated drinking water concentrations (EWDC) 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 EWDCs for chronic exposures is estimated to be 1.81 ppb for surface water and 0.005 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the DEEM-FCID. For acute dietary risk assessment, the peak water concentration value of 10.3 ppb was used to assess the contribution of drinking water. For chronic dietary risk assessment, the annual average concentration of 1.8 ppb was used to assess the contribution of 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 any specific use patterns that would result in residential exposure. No new residential uses are associated with the petitioned-for tolerances.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found fenpropathrin to share a common mechanism of toxicity with any other substances, and fenpropathrin does not appear to produce a toxic metabolite produced by other substances.

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 the pyrethroids have similar effects on all channels. The Agency does not have a clear understanding of effects on key downstream neuronal function, e.g., nerve excitability, nor does it understand how these key events interact to produce their compound-specific patterns of neurotoxicity. There is ongoing research by EPA and pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. When the results of the research are available, the Agency will consider this research and make a determination of common mechanism as a basis for assessing cumulative risk. Information regarding EPA’s procedures for cumulating effects from substances found to have a common mechanism can be found on EPA’s website at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(c) of FFDCFA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There are no concerns or residual uncertainties for pre-and/or post-natal toxicity resulting from exposure to fenpropathrin. There is no evidence (qualitative or quantitative) of increased susceptibility following *in utero* and/or pre-natal or post-natal exposure in adequate developmental toxicity studies in rats or rabbits, a 2-generation reproduction study in rats, and a developmental neurotoxicity study in rats.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for fenpropathrin is adequate for FQPA

determination. The database for fenpropathrin is not complete, but it does provide adequate information to characterize toxicity/endpoint selection for infants and children including acceptable acute neurotoxicity, subchronic neurotoxicity, and developmental neurotoxicity studies. Based on recently revised EPA Part 158 Guidelines, an immunotoxicology study in rats must be submitted to the Agency. However, because there was no indication of immunotoxicity in the toxicity database, an additional 10x database uncertainty factor is not considered necessary in order to be protective of potential immunotoxic effects.

ii. The toxicity data, including a developmental neurotoxicity study, showed no increase in qualitative or quantitative susceptibility in fetuses and pups with *in utero* and/or post-natal exposure to fenpropathrin.

iii. There are no residual uncertainties identified in the exposure databases. Dietary food exposure assessments were performed based on 100% PCT, tolerance-level residues for existing and proposed uses, and field trial data. The exposure databases (dietary food and drinking water) are complete and the exposure assessment for each potential exposure scenario includes all metabolites and/or degradates of concern and does not underestimate the potential exposure for infants and children. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenpropathrin in drinking water. These assessments will not underestimate the exposure and risks posed by fenpropathrin.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary

consumption of food and drinking water. Dietary (food + water) consumption is the only source of exposure to fenpropathrin that is expected to result in acute exposure. Therefore, the acute aggregate risk estimates are equivalent to the acute dietary exposure discussed in Unit III. Acute aggregate risk is below EPA's level of concern for the general U.S. population and all population subgroups. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenpropathrin will occupy 53% of the aPAD for children 1-2 years, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenpropathrin from food and water will utilize 41% of the cPAD for children 1-2 years, the population group receiving the greatest exposure. There are no residential uses for fenpropathrin.

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

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

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

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

5. *Aggregate cancer risk for U.S. population.* Aggregate cancer risk is not a concern because fenpropathrin is classified as "not likely to be carcinogenic to humans."

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

IV. Other Considerations

A. Analytical Enforcement Methodology

There are adequate enforcement methods for fenpropathrin. The methods use gas chromatography using an electron capture detector (GC/ECD), for the determination of fenpropathrin residues in/on plants (RM-22-4, revised 5/3/93) and animals (RM-22A-1). The limit of detection (LOD) for Method RM-22-4 is 0.01 ppm.

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

B. International Residue Limits

Codex and Mexican maximum residue limits (MRLs) are established for residues of fenpropathrin, but no limits are listed for the crop commodities addressed herein. No Canadian MRLs are established for fenpropathrin.

C. Revisions to Petitioned-For Tolerances

Based upon review of available data supporting these petitions, EPA revised the tolerance levels, added or deleted tolerances, corrected commodity definitions, or otherwise modified the petitions as proposed in the notice of filings, as follows:

- EPA did not include cherries in the proposed tolerance on fruit, stone, crop group 12 because of the significant difference in residue levels on cherries compared to other commodities in the crop group. Instead, EPA established an individual tolerance for cherry, sweet at 5.0 ppm, and cherry, tart at 5.0 ppm.

- Based on available field trials residue data, analyzed under the Guidance for Setting Pesticide Tolerances Based on Field Trial Data SOP, the Agency revised the tolerance level from 5.0 to 1.4 ppm for fruit, stone, group 12 (except cherry).

- EPA did not include pistachios in the proposed tolerance on tree nuts, crop group 14 because of pistachios are not currently part of that crop group. Instead EPA established an individual tolerance for pistachios at 0.10 ppm.

- Based on available field trials residue data, analyzed under the Guidance for Setting Pesticide Tolerances Based on Field Trial Data SOP, the Agency revised the tolerance level for almond, hulls from 5.0 to 4.5 ppm.

- Corrected commodity definition of the proposed tolerance on caneberry subgroup 13A to caneberry, subgroup 13-07A to reflect how the crop group is defined in the applicable regulations.

V. Conclusion

Therefore, tolerances are established for residues of the insecticide, fenpropathrin, (alpha-cyano-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate), in or on almond, hulls at 4.5 ppm; cherry, sweet at 5.0 ppm; cherry, tart at 5.0 ppm; fruit, stone, crop group 12 (except cherry) at 1.4 ppm; nut, tree, crop group 14 at 0.10 ppm; avocado at 1.0 ppm; black sapote at 1.0 ppm; canistel at 1.0 ppm; maney sapote at 1.0 ppm; mango at 1.0 ppm; papaya at 1.0 ppm; sapodilla at 1.0 ppm; star apple at 1.0; caneberry, subgroup 13-07A at 12.0 ppm; olive at 5.0 ppm; and pistachio at 0.10 ppm. In addition, the Agency is deleting a time-limited tolerance on currant at 15 ppm which had an expiration date of 12/31/2008.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by

Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: February 24, 2009.

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 by alphabetically adding the following commodities to the table in paragraph (a) and by removing the text in paragraph (b) and reserving the heading.

§ 180.466 Fenpropathrin; tolerances for residues.

Commodity	Parts per million
Almond, hulls	4.5
Avocado	1.0
Caneberry subgroup 13-07A.	12
Canistel	1.0
Cherry, sweet	5.0
Cherry, tart	5.0
Fruit, stone, crop group 12, except cherry.	1.4
Mango	1.0
Nut, tree, crop group 14.	0.10
Olive	5.0
Papaya	1.0
Pistachio	0.10
Sapodilla	1.0
Sapote, black	1.0
Sapote, mamey	1.0
Star apple	1.0

(b) Section 18 emergency exemptions. [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-1202; FRL-8403-7]

Propiconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of propiconazole in or on beet, garden, roots at 0.30 ppm; beet, garden, tops at