10.20 Miscellaneous Hazardous Materials (Hazard Class 9)

* * * * *

10.20.2 Mailability

[Revise the second sentence of 10.20.2 as follows:]

* * * A miscellaneous hazardous material that can qualify as an ORM–D material (until January 1, 2015) when intended for ground transportation, or a mailable air-eligible consumer commodity material when intended for air transportation, is permitted for domestic mail via air or surface transportation, subject to the applicable 49 CFR requirements.

10.20.3 Marking

[Revise 10.20.3 as follows:]

For surface transportation, the mailpiece must be plainly and durably marked on the address side with ''Surface Only'' or ''Surface Mail Only'' and ''ORM–D'' immediately following or below the proper shipping name (or with a DOT square-on-point marking under 10.8b). For air transportation, packages must bear the DOT square-on-point marking including the symbol ''Y,'' an approved DOT Class 9 hazardous material warning label, Identification Number ''ID8000,'' the proper shipping name ''Consumer Commodity,'' and a shipper's declaration for dangerous goods.

* * * * *

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

Stanley F. Mires,

Attorney, Legal Policy and Legislative Advice.

[FR Doc. 2012–28673 Filed 11–27–12; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0644; FRL–9366–1]

Fenpropathrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenpropathrin in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 28, 2012. Objections and requests for hearings must be received on or before January 28, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2009–0644, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; email address: *nollen.laura@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0644 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 28, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0644, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of October 7, 2009 (74 FR 51597) (FRL–8792–7), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7594) by IR–4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.466 be amended by establishing tolerances for

residues of the insecticide fenpropathrin, alpha-cyano-3-phenoxy-benzyl 2,2,3,3-tetramethylcyclopropanecarboxylate, in or on acerola, feijoa, guava, jaboticaba, passionfruit, starfruit and wax jambu at 1.5 parts per million (ppm); longan, lychee, pulasan, rambutan and Spanish lime at 3.0 ppm; atemoya, biriba, cherimoya, custard apple, ilama, soursop and sugar apple, at 1.0 ppm; and tea at 2.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR–4 by Valent USA Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerances for several commodities. The Agency has also revised the tolerance expression for all established commodities to be consistent with current Agency policy. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fenpropathrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenpropathrin 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.

Fenpropathrin is a member of the pyrethroid class of insecticides. Pyrethroids have historically been classified into two groups—Type I and Type II, based on chemical structure and toxicological effects. Type I pyrethroids induce in rats a syndrome consisting of aggressive sparring, altered sensitivity to external stimuli, hyperthermia, and fine tremors, progressing to whole-body tremors, and prostration (T-syndrome). Type II pyrethroids, which contain an alpha-cyano moiety, produce in rats a syndrome that includes pawing, burrowing, salivation, hypothermia, and coarse tremors leading to choreoathetosis (CS-syndrome). Fenpropathrin is a mixed type pyrethroid because the biochemical responses and resulting clinical signs of neurotoxicity are intermediate between those of Type I and Type II pyrethroids. The adverse outcome pathway shared by pyrethroids involves the ability to interact with voltage-gated sodium channels in the central and peripheral nervous systems, leading to changes in neuron firing and, ultimately, neurotoxicity.

Fenpropathrin exhibits high acute toxicity via the oral and dermal routes, but low toxicity via the inhalation route of exposure. Fenpropathrin is a mild eye irritant, but does not cause dermal irritation or skin sensitization. Toxicological effects characteristic of Type I pyrethroids were seen in most of the experimental toxicology studies including the acute, subchronic, and developmental neurotoxicity studies, subchronic studies in the rat and dog, the chronic carcinogenicity study in the rat, the developmental studies in the rat and rabbit, and in the 3-generation reproduction study in rats. Tremors were the most common indication of neurotoxicity; however, ataxia, increased sensitivity (e.g., heightened response) to external stimuli, convulsions, and increased auditory startle response were also observed.

In developmental toxicity studies in rats and rabbits, maternal toxicity included neurological effects such as ataxia, sensitivity to external stimuli, tremors in the rat, and flicking of forepaws in the rabbit. Developmental effects were limited to incomplete or asymmetrical ossification of sternebrae at the maternally toxic dose in the rat. There were no developmental effects in the rabbit. There were no indications of immunotoxicity in any of the guideline studies, including the immunotoxicity study in rats. In a 3-generation reproduction study in the rat, maternal and offspring effects were observed at the mid- and high-dose. At the high dose, maternal effects included increased deaths and clinical signs of toxicity (tremors, muscle twitches, and increased sensitivity) during lactation. Pup deaths were noted at this level. At the mid-dose, minimal signs of treatment-related effects were observed for both adults and pups, reducing concern for quantitative or qualitative sensitivity.

There was no evidence of carcinogenicity in either the rat or mouse long-term dietary studies, nor was there any mutagenic activity in bacteria or cultured mammalian cells. Fenpropathrin has been classified as ''not likely to be carcinogenic to humans.''

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 the document, ''Fenpropathrin. Human Health Risk Assessment for Section 3 Registration on Tropical Fruit and a Request for a Tolerance without U.S. Registration on Tea'' at pp 40–45 in docket ID number EPA–HQ–OPP–2009–0644.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin

of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.* A summary of the toxicological endpoints for Fenpropathrin used for human risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FENPROPATHRIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD for risk assessment	Study and toxicological effects
Acute dietary (General population, including children ≥ 6 years old).	Wolansky $BMDL_{1SD}$ = 5.0 mg/kg. UF_A = 10X UF_H = 10X FQPA SF = 1X	aRfD = 0.05 mg/kg/day. aPAD = 0.05 mg/kg/day.	Wolansky BMD_{1SD} = 6.4 mg/kg based on decreased motor activity.
Acute dietary (< 6 years old)	Wolansky $BMDL_{1SD}$ = 5.0 mg/kg. UF_A = 10X UF_H = 10X FQPA SF = 3X	aRfD = 0.05 mg/kg/day. aPAD = 0.017 mg/kg/day.	Wolansky BMD_{1SD} = 6.4 mg/kg based on decreased motor activity.
Chronic dietary (All populations)	Because of the rapid reversibility of the most sensitive neurotoxicity endpoint used for quantifying risks, there is no increase in hazard with increasing dosing duration. Therefore, the acute dietary endpoint is protective of the endpoints from repeat dosing studies, including chronic dietary exposures.		
Cancer (Oral, dermal, inhalation)	Fenpropathrin has been classified as "not likely to be carcinogenic to humans." Cancer risk is not of concern.		

FQPA SF = Food Quality Protection Act Safety Factor. mg/kg/day = milligram/kilogram/day. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). BMD = Benchmark Dose Analysis. BMD_{1SD} = dose level where effect is 1SD from control value. $BMDL_{1SD}$ = lower 95% confidence limit of the BMD value.

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. Such effects were identified for fenpropathrin. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA utilized percent crop treated (PCT) estimates and tolerance level residues, distributions of field trial values, and distributions of Pesticide Data Program (PDP) monitoring data.

Residue distributions were used for the commodities that made the most significant contributions to the risk estimates. Distributions of USDA's PDP monitoring data from 2007 through 2010 were used for broccoli (translated to Chinese mustard cabbage and cauliflower), watermelon, squash, oranges (translated to tangerines), apples, apple juice, pears, blueberries (translated to huckleberries), grapes, grape juice, and strawberries. Distributions of field trial data were used for cherries, peaches, plums, grapefruit, raspberries, blackberries, apricots, cabbage, papaya, olives, tomatoes, cucumbers, Brussels sprouts, and guava. Tolerance-level residues were assumed for all other commodities having existing or proposed tolerances. Dietary Exposure Evaluation Model (DEEM) default processing factors were used for those commodities for which they were available. In some cases, empirical processing factors were used.

ii. *Chronic exposure.* Based on the data summarized in Unit III.A., there is no bincrease in hazard from repeated exposures to fenpropathrin; the acute dietary exposure assessment is protective for chronic dietary exposures because acute exposure levels are higher than chronic exposure levels. Accordingly, a dietary exposure assessment for the purpose of assessing chronic dietary risk was not conducted.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fenpropathrin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA 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 FFDCA section 408(b)(2)(E) and authorized under FFDCA 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 FFDCA 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

Apples, 15%; apricots, 2.5%; blueberries, 2.5%; broccoli, 2.5%; Brussels sprouts, 10%; cabbage, 2.5%; cauliflower, 2.5%; cherries, 5%; cotton, 2.5%; cucumbers, 2.5%; grapefruit, 35%; grapes, 10%; nectarines, 2.5%; oranges, 35%; peaches, 2.5%; pears, 10%; plums, 2.5%; prune plums, 2.5%; squash, 2.5%; strawberries, 50%; tangerines, 15%; tomatoes, 10%; and watermelons, 2.5%.

In most cases, EPA uses available data from U.S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 to 7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, 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 reliable information on the regional consumption of food to which fenpropathrin may be applied in a particular area.

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) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) 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.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 10.3 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fenpropathrin is not registered for any specific use patterns that would result in residential exposure.

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

The Agency is required to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. The Agency has determined that the pyrethroids and pyrethrins, including fenpropathrin, share a common mechanism of toxicity. The members of this group share the ability to interact with voltage-gated sodium channels, ultimately leading to neurotoxicity. The cumulative risk assessment for the pyrethroids/pyrethrins was published in the November 9, 2011 issue of the **Federal Register** (76 FR 69726) (FRL 8888–9), and is available at *http://www.regulations.gov* in the public docket, EPA–HQ–OPP–2011–0746. Further information about the determination that pyrethroids and pyrethrins share a common mechanism of toxicity may be found in document ID: EPA–HQ- OPP–2008–0489–0006.

The Agency has conducted a quantitative analysis of the proposed tolerances for fenpropathrin and has determined that it will not contribute significantly or change the overall findings presented in the pyrethroid cumulative risk assessment. In the cumulative assessment for pyrethroids, residential exposures were the greatest contributor to the total exposure. As there are no residential uses for fenpropathrin, the proposed new uses will have no impact on the residential component of the cumulative risk estimates.

Dietary exposures make a minor contribution to the total pyrethroid exposure. The dietary exposure assessment performed in support of the pyrethroid cumulative assessment was much more highly refined than that performed for the single chemical, fenpropathrin. In addition, for the fenpropathrin risk assessment, the most sensitive apical endpoint in the fenpropathrin database was selected to derive the POD. Additionally, the POD selected for fenpropathrin is specific to fenpropathrin, whereas the POD selected for the cumulative assessment was based on common mechanism of action data that are appropriate for all 20 pyrethroids included in the cumulative assessment. The proposed food uses of fenpropathrin will not contribute significantly or change the overall findings in the pyrethroid cumulative risk assessment, as the dietary risks are a minor component of total pyrethroid cumulative risk. For information regarding EPA's efforts to evaluate the risk of exposure to pyrethroids, refer to *http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.*

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* The fenpropathrin toxicity database includes developmental toxicity studies in rats and rabbits and a 3-generation reproduction study in rats, and a developmental neurotoxicity (DNT) study in rats. There was no evidence of increased qualitative or quantitative susceptibility noted in any of these studies. This lack of susceptibility is consistent with the results of the guideline prenatal and postnatal testing for other pyrethroid pesticides.

There are several *in vitro* and *in vivo* studies that indicate pharmacodynamic contributions to pyrethroid toxicity are not age-dependent. A study of the toxicity database for pyrethroid chemicals also noted no residual uncertainties regarding age-related sensitivities for the young, based on the absence of prenatal sensitivity observed in 76 guideline studies for 24 pyrethroids and the scientific literature. However, high-dose studies at LD_{50} doses noted that younger animals were more susceptible to the toxicity of pyrethroids. These age-related differences in toxicity are principally due to age-dependent pharmacokinetics; the activity of enzymes associated with the metabolism of pyrethroids increases with age. Nonetheless, the typical environmental exposures to pyrethroids are not expected to overwhelm the clearance capacity in juveniles. In support, at a dose of 4.0 milligrams/kilogram (mg/kg) for deltamethrin (near the Wolansky study LOAEL value of 3.0 mg/kg for deltamethrin), the change in the acoustic startle response was similar between adult and young rats.

3. *Conclusion.* EPA is reducing the FQPA SF to 3X for infants and children less than 6 years of age. For the general population, including children greater than 6 years of age, EPA is reducing the FQPA SF to 1X. The decisions regarding the FQPA SF being used are based on the following considerations:

i. The toxicity database for fenpropathrin is not complete. While the database is considered to be complete with respect to the guideline toxicity studies for fenpropathrin, EPA lacks additional data to address the potential for juvenile sensitivity to all pyrethroids. In light of the literature studies indicating a possibility of increased sensitivity to fenpropathrin in juvenile rats at high doses, EPA has requested proposals for study protocols which could identify and quantify fenpropathrin's potential juvenile sensitivity. The reasons discussed in Unit III.D.3.ii, and the uncertainty regarding the protectiveness of the intraspecies uncertainty factor raised by the literature studies warrant application of an additional 3X for risk assessments for infants and children less than 6 years of age.

ii. There is no evidence that fenpropathrin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in a 3-generation rat reproduction study. This is consistent with the results of the guideline pre-natal and postnatal testing for other pyrethroid pesticides. There are, however, high dose LD_{50} studies (studies assessing what dose results in lethality to 50 percent of the tested population) in the scientific literature indicating that pyrethroids can result in increased quantitative sensitivity in the young. Examination of pharmacokinetic and pharmacodynamic data indicates that the sensitivity observed at high doses is related to pyrethroid age-dependent pharmacokinetics, the activity of enzymes associated with the metabolism of pyrethroids. Predictive pharmacokinetic models indicate that the differential adult-juvenile pharmacokinetics will result in otherwise equivalent administered doses for adults and juveniles producing a 3X greater dose at the target organ in juveniles compared to adults.

No evidence of increased quantitative or qualitative susceptibility was seen in the pyrethroid scientific literature related to pharmacodynamics (the effect of pyrethroids at the target tissue) both with regard to interspecies differences between rats and humans and to differences between juveniles and adults. Specifically, there are *in vitro* pharmacodynamic data and *in vivo* data indicating similar responses between adult and juvenile rats at low doses and data indicating that the rat is a conservative model compared to the human based on species-specific pharmacodynamics of homologous sodium channel isoforms in rats and humans.

In light of the high dose literature studies showing juvenile sensitivity to pyrethroids and the absence of the requested data on juvenile sensitivity to pyrethroids, EPA is retaining a 3X additional safety factor as estimated by pharmacokinetic modeling. For several reasons, EPA concludes there are reliable data showing that a 3X factor is protective of the safety of infants and children. First, the high doses that produced juvenile sensitivity in the literature studies are well above normal dietary exposure levels of pyrethroids to juveniles and these lower levels of exposure are not expected to overwhelm the ability to metabolize pyrethroids as occurred with the high doses used in the literature studies. This is confirmed by the lack of a finding of increased sensitivity in prenatal and postnatal guideline studies in any pyrethroid, including fenpropathrin, despite the relatively high doses used in those studies. Second, the portions of both the inter- and intraspecies uncertainty factors that account for potential pharmacodynamic differences (generally considered to be approximately 3X for each factor) are likely to overstate the risk of inter- and intraspecies pharmacodynamic differences given the data showing similarities in pharmacodynamics between juveniles and adults and between humans and rats. Finally, as indicated, pharmacokinetic modeling only predicts a 3X difference between juveniles and adults.

iii. There are no residual uncertainties identified in the exposure databases. Although the acute dietary exposure estimates are refined, as described in Unit III.C.1.i., the exposure estimates will not underestimate risk for the established and proposed uses of fenpropathrin. The residue levels used are based on distributions of residues from field trial data, monitoring data reflecting actual residues found in the food supply, and tolerance-level residues for several commodities; the use of estimated PCT information; and, when appropriate, processing factors measured in processing studies or default high-end factors representing the maximum concentration of residue into a processed commodity. 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.

Further information about the reevaluation of the FQPA SF for

pyrethroids may be found in document ID: EPA–HQ–OPP–2011–0746–0011, at regulations.gov.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenpropathrin will occupy 97% of the aPAD for children 3 to 5 years old, the population group receiving the greatest exposure from the dietary assessment for infants and children less than 6 years old; and 27% of the aPAD for children 6 to 12 years old, the population group receiving the greatest exposure from the dietary assessment for the general population other than children less than 6 years old.

2. *Chronic risk.* Based on the data summarized in Unit III.A., there is no increase in hazard with increasing dosing duration. Furthermore, chronic dietary exposures will be lower than acute exposures. Therefore, the acute aggregate assessment is protective of potential chronic aggregate exposures.

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). A short-term adverse effect was identified; however, fenpropathrin is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and acute dietary exposure has already been assessed under the appropriately protective aPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the acute dietary risk assessment for evaluating short-term risk for fenpropathrin.

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). Because no intermediate-term adverse effect was identified, fenpropathrin is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fenpropathrin is not expected to pose a cancer risk 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

An adequate enforcement methodology utilizing gas chromatography with electron capture detection (GC/ECD, Residue Method Number RM–22–4) is available to enforce the tolerance expression.

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

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for fenpropathrin in or on tea, green and black at 2.0 ppm. Using the Organization for Economic Cooperation and Development (OECD) MRL calculation procedures, the recommended U.S. tolerance for tea, dried would be 3.0 ppm. However, for the purposes of harmonization of the U.S. tolerance with the established Codex MRL, EPA is recommending the tolerance of 2.0 ppm for tea, dried. The Agency considers this tolerance level to be adequate because the highest field trial value noted for tea, dried was 1.38 ppm.

C. Revisions to Petitioned-for Tolerances

Based on the data supporting the petitions, EPA revised the proposed tolerances on acerola, feijoa, guava, jaboticaba, passionfruit, startfruit and wax jambu from 1.5 ppm to 3.0 ppm; longan, lychee, pulasan, rambutan, and Spanish lime from 3.0 ppm to 7.0 ppm; and atemoya, birba, cherimoya, custard apple, ilama, soursop, and sugar apple, from 1.0 ppm to 1.5 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the OECD tolerance calculation procedures. EPA also revised the proposed commodity definition for tea to tea, dried in order to reflect the Agency's commodity nomenclature.

Finally, the Agency has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of fenpropathrin not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of fenpropathrin, alpha-cyano-3-phenoxy-benzyl 2,2,3,3-tetramethylcyclopropanecarboxylate, in or on acerola, feijoa, guava, jaboticaba, passionfruit, starfruit and wax jambu at 3.0 ppm; longan, lychee, pulasan, rambutan and Spanish lime, at 7.0 ppm; atemoya, biriba, cherimoya, custard apple, ilama, soursop and sugar apple, at 1.5 ppm; and tea, dried at 2.0 ppm.

VI. Statutory and Executive Order Reviews

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). 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This 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 FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this 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) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: November 15, 2012.

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. In § 180.466, paragraph (a), revise the introductory text, alphabetically add the following commodities and footnote 1 to the table to read as follows:

§ 180.466 Fenpropathrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of fenpropathrin, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only fenpropathrin (alpha-cyano-3-phenoxy-benzyl 2,2,3,3 tetramethylcyclopropanecarboxylate).

Commodity	Parts per million
Acerola	3.0
* * * * *	
Atemoya	1.5
* * * * *	
Biriba	1.5
* * * * *	
Cherimoya	1.5
* * * * *	
Custard apple	1.5
* * * * *	
Feijoa	3.0
* * * * *	
Guava	3.0
* * * * *	
Ilama	1.5
Jaboticaba	3.0
* * * * *	
Longan	7.0
Lychee	7.0
* * * * *	
Passionfruit	3.0
* * * * *	
Pulasan	7.0
Rambutan	7.0
* * * * *	
Soursop	1.5
Spanish lime	7.0
* * * * *	
Starfruit	3.0
* * * * *	
Sugar apple	1.5
Tea, dried[1]	2.0
* * * * *	
Wax jambu	3.0

[1] There are no U.S. registrations as of November 28, 2012, for the use of fenpropathrin on tea, dried.

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[FR Doc. 2012–28721 Filed 11–27–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0060; FRL–9365–1]

Dinotefuran; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dinotefuran in or on rice grain, egg, and poultry meat byproducts. Mitsui Chemicals Agro Inc., c/o Landis International, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 28, 2012. Objections and requests for hearings must be received on or before January 28, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0060, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30