703 Nonprofit Standard Mail and Other Unique Eligibility

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2.0 Oversea Military Mail

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2.6 Priority Mail Express Military Service (PMEMS)

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[Revise the heading and text of 2.6.6 as follows:]

2.6.6 To APO/FPO and DPO Destinations

Under PMEMS, items mailed to APO/FPO and DPO destinations (from the United States) are available for delivery at the destination APO/FPO or DPO Post Office by 3 p.m. on the designated delivery day unless the designated delivery day is a weekend or holiday; in such cases, the item is available for delivery on the next business day.

[Revise the heading and text of 2.6.7 as follows:]

2.6.7 From APO/FPO and DPO Destinations

Under PMEMS, items mailed from APO/FPO and DPO locations (going to the United States) are delivered to an addressee within the delivery area of the destination Post Office by 3 p.m. on the designated delivery day.

2.6.8 Mailing Label

[Revise the first sentence of 2.6.8 as follows:]

For each PMEMS item, the mailer must complete mailing Label 11–B or Label 11–F. * * *

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705 Advanced Preparation and Special Postage Payment Systems

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2.0 Manifest Mailing System

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2.4 Authorization

2.4.1 Application

[Revise the text of 2.4.1 as follows:]

The mailer must submit an MMS application and supporting documentation as specified on the application to the postmaster of each Post Office where mailings will be deposited and under the publications as follows:

a. Publication 401, *Guide to the Manifest Mailing System,* contains an application to mail using an MMS.

b. Publication 205, *Electronic Verification System Technical Guide,* provides the eVS application procedures for mailers. Customers using an Electronic Manifesting Solution for Parcels must also establish a user account and mailer agreement with USPS in the Business Customer Gateway at *https://gateway.usps.com.*

* * * * *

2.6 Priority Mail Express Manifesting Agreements

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2.6.2 What May Be Manifested

[Revise the first sentence of 2.6.2 as follows:]

PMEM may be used to pay postage for Priority Mail Express and Priority Mail Express Military Service to qualifying APO/FPO and DPO addresses. * * *

* * * * *

2.8 Applications, Agreement Renewals, Modifications, Suspensions, and Cancellations

* * * The application for PMEM must be accompanied by the following:

[Revise item 2.8.1b as follows:]

b. A copy of Form 5639 showing that a USPS Corporate Account has been established.

* * * * *

18.0 Priority Mail Express Open and Distribute and Priority Mail Open and Distribute

18.1 Prices and Fees

18.1.1 Basis of Price

The basis of price for Priority Mail Express and Priority Mail Open and Distribute is as follows:

[Revise the first sentence of item 18.1.1a as follows:]

a. Priority Mail Express postage is based on the zone and weight of the contents of the Open and Distribute shipment. * * *

* * * * *

[Revise the first sentence of item 18.1.1c as follows:]

c. Except as provided above, Priority Mail postage is based on the zone and weight of the contents of the Open and Distribute shipment.

* * * * *

[Delete 19.0, Express Mail Reshipment Service, in its entirety. Renumber 705.20 through 705.26 as 705.19 through 705.25.]

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708 Technical Specifications

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10.0 Postal Zones

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10.4 Specific Zones

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10.4.2 Nonlocal Zone

Nonlocal zones are defined as:

* * * * *

[Add new item 10.4.2i as follows:]

h. Zone 9 includes the destinations listed in DMM 608.2.2 (Republic of Palau, Federated States of Micronesia, and Republic of the Marshall Islands).

* * * * *

Index and Appendices

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Forms Glossary

[Delete the following forms:]

PS Form 1509, *Sender's Application for Recall of Mail*

PS Form 5541, *Pickup Service Statement—PME, GXG, PM, or Standard Post*

PS Form 5625, *Priority Mail Express Custom Designed Service Receipt*

PS Form 5637, *USPS Corporate Account/Custom Designed Agreement*

* * * * *

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. 2013–27728 Filed 11–19–13; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0899; FRL–9902–44]

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. This regulation additionally removes several permanent tolerances as they will be superseded by the tolerances established by 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 20, 2013. Objections and requests for hearings must be received on or before January 21, 2014, 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–2012–0899, 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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@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://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OPPTS test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2012–0899 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 21, 2014. 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–2012–0899, 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.html.*

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 Tolerances

In the **Federal Register** of February 15, 2013 (78 FR 11126) (FRL–9378–4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8107) by IR–4,500 College Rd. 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-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate, in or on barley, grain at 0.04 parts per million (ppm); barley, hay at 3.0 ppm; barley, straw at 2.0 ppm; berry, low-growing, subgroup 13–07G at 2.0 ppm; bushberry subgroup 13–07B at 3.0 ppm; fruit, citrus, group 10–10 at 2.0 ppm; fruit, pome, group 11–10 at 5.0 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 5.0 ppm; and vegetable, fruiting, group 8–10 at 1.0 ppm. The petition additionally requested the removal of the following established tolerances in 40 CFR 180.466 for fenpropathrin as they will be superseded by new tolerances, if established: Fruit, citrus, group 10; fruit, pome, group 11; bushberry subgroup 13B; grape; juneberry; salal; strawberry; and vegetable, fruiting, group 8.

That document 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 determined that the established tolerance for lingonberry will also be removed. The reason for this change is 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, which lack an alpha-cyano moiety, induce in rats a syndrome consisting of aggressive sparring, altered sensitivity to external stimuli, hyperthermia, and fine tremor progressing to whole-body tremor 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 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. 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 were no indications of immunotoxicity in any of the guideline studies, including the immunotoxicity study in rats.

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 toxicological points of departure (POD) derived from the BMDL (statistical lower confidence limit on the dose at the benchmark dose) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Fenpropathrin. Human Health Risk Assessment for the Proposed Section 3 Registration on Barley and the Request to Update Several Existing Crop Groups with Revised Crop Grouping Definitions'' starting at p. 12, in docket ID number EPA–HQ–OPP–2012–0899.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological 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. For fenopropathrin, the PODs are developed based on a careful analysis of the doses in each toxicological study; a benchmark dose analysis was conducted to derive the BMDL. 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 discussed in Unit III.B. of the final rule published in the **Federal Register** of November 28, 2012 (77 FR 70902) (FRL–9366–1).

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 United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). 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 (i.e., the ''risk drivers''). Monitoring data were used for risk drivers when they were available; however, field trial data were used for the remaining risk drivers. Distributions of monitoring data values were used for the following risk drivers: Apple juice, apples, blackberries, blueberries, broccoli, cauliflower, Chinese mustard cabbage, grape juice, grapes, huckleberries, oranges, pears, raspberries, squash, strawberries, tangerines, and watermelon. Monitoring

data from the years 2007 through 2010, inclusive, were used. Broccoli PDP data were translated to Chinese mustard cabbage and cauliflower. Orange PDP data were translated to tangerines. Blueberry PDP data were translated to blackberries, huckleberries, and raspberries. Finally, strawberry PDP data were translated to cranberries. Distributions of field trial data were used for apricot juice, apricots, Brussels sprouts, cabbage, cherries, cherry juice, Chinese napa cabbage, cucumbers, grapefruit, grapefruit juice, guava, mango, mango juice, nectarines, olives, papaya, papaya juice, passion fruit, passion fruit juice, peach juice, peaches, plums, prune plum juice, prune plums, tomato juice, and tomatoes. For most processed commodities, DEEM (Dietary Exposure Evaluation Model) 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 increase 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 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 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 United States 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 6–7 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 one. 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), 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 **Federal Register** of November 9, 2011 (76 FR 69726) (FRL 8888–9), and is available at *http://www.regulations.gov* in docket ID number 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 number EPA–HQ–OPP–2008–0489–0006.

Fenpropathrin was included in the cumulative risk assessment for pyrethrins and pyrethroids. The proposed new uses of fenpropathrin will not significantly impact the cumulative assessment because, in the cumulative assessment, residential exposure was the greatest contributor to the total exposure. As there are no new residential uses for the 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 total pyrethroid exposure. The dietary exposure assessment performed in support of the pyrethroid cumulative was much more highly refined than that performed for the single chemical. The dietary exposure assessment for the single chemical included conservative assumptions, using field trial data for many commodities, including the proposed new uses with the assumption of 100 PCT, and the most sensitive apical endpoint in the fenpropathrin hazard database was selected to derive the POD. Additionally, the POD selected for fenpropathrin is specific to the 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.

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 SF 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 the rat and rabbit, a 3-generation reproduction study in the rat, 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 pre- and postnatal testing for other pyrethroid pesticides.

High-dose LD_{50} studies (studies assessing what dose results in lethality to 50% of the tested population) in the scientific literature indicate that pyrethroids can result in increased quantitative sensitivity in the young, specifically in the form of neurotoxicity. 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. With otherwise equivalent administered doses for adults and juveniles, predictive pharmacokinetic models indicate that the differential adult-juvenile pharmacokinetics will result in 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) with regard 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.

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 SFs being used are based on the following considerations:

i. While the database is considered to be complete with respect to the guideline toxicity studies for fenpropathrin, EPA lacks additional data to fully characterize the potential for juvenile sensitivity to neurotoxic effects of pyrethroids. In light of the literature studies indicating a possibility of increased sensitivity in juvenile rats at high doses, EPA identified a need, and requested proposals for, additional non-guideline studies to evaluate the potential for sensitivity in juvenile rats. A group of pyrethroid registrants is currently conducting those studies. Pending the results of those studies, however, the available toxicity studies for fenpropathrin can be used to characterize toxic effects including potential developmental and reproductive toxicity, immunotoxicity, and neurotoxicity. Acceptable developmental toxicity studies in rats and rabbits, reproduction studies in rats, neurotoxicity studies (acute, subchronic, and developmental) in rats, and immunotoxicity studies in rats are available. In addition, a route-specific dermal toxicity study is available, and the inhalation study has been waived.

ii. After reviewing the extensive body of data and peer-reviewed literature on pyrethroids, the Agency has reached a number of conclusions regarding fetal and juvenile sensitivity for pyrethroids, including the following:

- Based on an evaluation of over 70 guideline toxicity studies for 24 pyrethroids submitted to the Agency, including prenatal developmental toxicity studies in rats and rabbits, and pre- and postnatal multi-generation reproduction toxicity studies and DNTs in rats in support of pyrethroid registrations, there is no evidence that pyrethroids directly impact developing fetuses. None of the studies show any indications of fetal toxicity at doses that do not cause maternal toxicity.
- Increased susceptibility was seen in offspring animals in the DNT study with the pyrethroid zeta-cypermethrin (decreased pup body weights) and DNT and reproduction studies with another pyrethroid beta-cyfluthrin (decreased body weights and tremors). However, the reductions in body weight and the other non-specific effects occur at

higher doses than neurotoxicity, the effect of concern for pyrethroids. The available developmental and reproduction guideline studies in rats with zeta-cypermethrin did not show increased sensitivity in the young to neurotoxic effects. Overall, findings of increased sensitivity in juvenile animals in pyrethroid studies are rare. Therefore, the residual concern for the postnatal effects is reduced.

• High-dose LD_{50} studies (studies assessing what dose results in lethality to 50% of the tested population) in the scientific literature indicate that pyrethroids can result in increased quantitative sensitivity to juvenile animals. 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. Furthermore, a rat physiologically-based pharmacokinetic (PBPK) model predicts a 3-fold increase of pyrethroid concentration in juvenile brain compared to adults at high doses.

• *In vitro* pharmacodynamic data and *in vivo* data indicate that adult and juvenile rats have similar responses to pyrethroids at low doses and therefore juvenile sensitivity is not expected at relevant environmental exposures. Further, data also show that the rat is a conservative model compared to the human based on species-specific pharmacodynamics of homologous sodium channel isoforms.

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.

Taking all of this information into account, EPA has reduced the FQPA SF for women of child-bearing age because there is no evidence in the over 70 guideline toxicity studies submitted to the Agency that pyrethroids directly impact developing fetuses. Additionally, none of the studies show any indications of fetal toxicity at doses that do not cause maternal toxicity. Because there remains some uncertainty as to juvenile sensitivity due to the findings in the high-dose LD_{50} studies, EPA is retaining a 3X FQPA SF for infants and children less than 6 years of age. By age 6, the metabolic system is expected to be at or near adult levels thus reducing concerns for potential age-dependant sensitivity related to pharmacokinetics; therefore for children over 6, 1X is appropriate. Although EPA is seeking additional data to further characterize the potential neurotoxicity for pyrethroids, EPA has reliable data that show that reducing the FQPA SF to 3X will protect the safety of infants and children less than 6 years old. These data include:

a. Data from developmental, reproductive, and DNT guideline studies with fenpropathrin that show no sensitivity.

b. Data showing that the potential sensitivity at high doses is likely due to pharmacokinetics.

c. A rat PBPK model predicting a 3-fold increase of pyrethroid concentration in juvenile brain compared to adults at high doses due to age-dependent pharmacokinetics.

d. Data indicating that the rat is a conservative model compared to the human based on species-specific pharmacodynamics of homologous sodium channel isoforms.

For several reasons, EPA concludes these data show that a 3X factor is protective of the safety of infants and children less than 6 years of age. First, it is likely that the extensive guideline studies with pyrethroids, which indicate that increased sensitivity in juvenile animals in pyrethroid studies is rare, better characterize the potential sensitivity of juvenile animals than the LD_{50} studies. The high doses that produced juvenile sensitivity in the literature studies are well above normal dietary or residential exposure levels of pyrethroids to juveniles and lower levels of exposure anticipated from dietary and residential uses are not expected to overwhelm the juvenile's ability to metabolize pyrethroids, as occurred with the high doses used in the literature studies. The fact that a greater sensitivity to the neurotoxicity of pyrethroids is not found in guideline studies following *in utero* exposures (based on 76 studies for 24 pyrethroids) supports this conclusion, despite the relatively high doses used in the studies. Second, *in vitro* data indicate similar pharmacodynamic response to pyrethroids between juvenile and adult rats. Finally, as indicated, pharmacokinetic modeling only predicts a 3X difference between juveniles and adults. Therefore, the FQPA SF of 3X is protective of potential juvenile sensitivity.

Further information about the reevaluation of the FQPA SF for pyrethroids may be found in document ID number EPA–HQ–OPP–2011–0746–0011.

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-, intermediate-, 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 93% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure from the dietary assessment for infants and children less than 6 years old; and 20% 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 dose duration. 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

Adequate enforcement methodology utilizing gas chromatography with electron capture detector (GC/ECD), Residue Method Numbers RM–22–4 (plants) and RM–22A–1 (animals), 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.

Codex has established MRLs for tomatoes, sweet peppers, dried chili peppers, eggplant, grapes, and pome fruits. The MRLs for tomatoes, sweet peppers, grapes, and pome fruits are harmonized with the U.S. tolerances for the corresponding crop groups or subgroups. Codex MRLs for dried chili peppers (10 ppm) and eggplant (0.2 ppm) cannot be harmonized with the U.S. tolerance for the fruiting vegetable crop group (1.0 ppm), of which those commodities are a part. The Codex MRL for eggplant is lower than the recommended corresponding U.S. tolerance. Because the permitted domestic use on eggplant in accordance with the approved pesticide label results in residue levels higher than the Codex MRLs, the U.S. tolerance cannot be harmonized (lowered) since doing so would result in residues in excess of the approved tolerance in spite of use consistent with label directions. Concerning dried chili peppers, EPA, under its Residue Chemistry Test Guidelines (OPPTS 860.1000), does not set tolerances for dried chili peppers. Rather, residues on dried chili peppers would be covered under tolerances for non-bell peppers, which, for this chemical, are captured by the fruiting vegetable crop group tolerance. Under that U.S. tolerance, residues of fenpropathrin on dried chili peppers would be covered up to 1.0 ppm; residues in excess of that level would only be covered if EPA established a separate tolerance for them. At this time, however, EPA does not have data to support establishing a tolerance for dried chili peppers at 10 ppm.

C. Revisions to Petitioned-For Tolerances

Based on the data submitted with the petition, EPA is also removing the established tolerance for lingonberry. The Agency is removing this tolerance because it will be superseded by the new tolerance for bushberry subgroup 13–07B, established by this document. The removal does not substantively affect whether residues of fenpropathrin may be present on lingonberry. The new bushberry subgroup 13–07B tolerance is at the same level as the lingonberry tolerance being removed—3.0 ppm.

V. Conclusion

Therefore, tolerances are established for residues of fenpropathrin, alpha-cyano-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate, in or on barley, grain at 0.04 ppm; barley, hay at 3.0 ppm; barley, straw at 2.0 ppm; berry, low-growing, subgroup 13–07G at 2.0 ppm; bushberry subgroup 13–07B at 3.0 ppm; fruit, citrus, group 10–10 at 2.0 ppm; fruit, pome, group 11–10 at 5.0 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 5.0 ppm; and vegetable, fruiting, group 8–10 at 1.0 ppm. Additionally, this document removes the established tolerances of fenpropathrin in or on fruit, citrus, group 10; fruit, pome, group 11; bushberry subgroup 13B; grape; juneberry; lingonberry; salal; strawberry; and vegetable, fruiting, group 8.

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 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.

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 7, 2013.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.466:

■ a. Remove the entries for ''Bushberry subgroup 13B,'' ''Fruit, citrus, group 10,'' ''Fruit, pome, group 11,'' ''Grape,'' ''Juneberry,'' ''Lingonberry,'' ''Salal,'' ''Strawberry,'' and ''Vegetable, fruiting, group 8'' from the table in paragraph (a).

■ b. Add alphabetically the following entries to the table in paragraph (a).

The amendments read as follows:

§ 180.466 Fenpropathrin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Barley, grain	0.04
Barley, hay	3.0
Barley, straw	2.0
Berry, low growing, subgroup 13–07G	2.0
* * * * *	
Bushberry subgroup 13–07B	3.0
* * * * *	
Fruit, citrus, group 10–10	2.0
Fruit, pome, group 11–10	5.0
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	5.0
* * * * *	
Vegetable, fruiting, group 8–10	1.0
* * * * *	

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[FR Doc. 2013–27680 Filed 11–19–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2013–0005: 4500030113]

RIN 1018–AZ28

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Jemez Mountains Salamander

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, designate critical habitat for the Jemez Mountains salamander (*Plethodon neomexicanus*) under the Endangered Species Act of 1973 (Act), as amended. In total, we are designating as critical habitat for this species approximately 90,716 acres (36,711 hectares) in Los Alamos, Rio Arriba, and Sandoval Counties, New Mexico. The effect of this regulation is to conserve the Jemez Mountains salamander's habitat under the Act.

DATES: This rule is effective on December 20, 2013.

ADDRESSES: This final rule is available on the Internet at *http://www.fws.gov/southwest/es/NewMexico/index.cfm* and at *http://www.regulations.gov* at Docket No. FWS–R2–ES–2013–0005. Comments and materials we received, as well as supporting documentation used in preparing this final rule, are available for public inspection, by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office, 2105 Osuna NE., Albuquerque, NM 87113; telephone 505–346–2525; or facsimile 505–346–2542.

The coordinates or plot points or both from which the maps are generated are included in the administrative record for this critical habitat designation and are available at *http://www.fws.gov/southwest/es/NewMexico/index.cfm,* at *http://www.regulations.gov* at Docket No. FWS–R2–ES–2013–0005, and at the New Mexico Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**). Any additional tools or supporting information that we developed for this critical habitat designation are also available at the Fish and Wildlife Service Web site and Field Office set out above, and may also be included in the preamble of this rule or at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Wally Murphy, Field Supervisor, U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office, 2105 Osuna NE., Albuquerque, NM 87113; by telephone 505–346–2525; or by facsimile 505–346–2542. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Endangered Species Act (Act), any species that is determined to be an endangered or threatened species requires critical habitat to be designated, to the maximum extent prudent and determinable. Designations and revisions of critical habitat can only be completed by issuing a rule.

We listed the Jemez Mountains salamander as an endangered species on September 10, 2013 (78 FR 55599). This is a final rule to designate critical habitat for the Jemez Mountains salamander. Section 4(b)(2) of the Act states that the Secretary shall designate critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat.

The critical habitat areas we are designating in this rule constitute our