

| Commodity  | Parts per million |
|--|-------------------|
| Honeysuckle, edible .....  | 7.0               |
| Jostaberry .....   | 7.0               |
| Juneberry .....  | 7.0               |
| Lingonberry .....  | 7.0               |
| Native currant .....   | 7.0               |
| Pea and bean, dried shelled, except soybean, subgroup 6C, except pea ..... | 0.02              |
| Pea and bean, succulent shelled, subgroup 6B, except pea .....             | 0.04              |
| * * * *  | *                 |
| Salal .....  | 7.0               |
| Sea buckthorn .....  | 7.0               |
| Turnip, greens .....   | 0.01              |
| Vegetable, Brassica leafy, group 5 .....                                   | 0.01              |
| Vegetable, legume, edible-podded, subgroup 6A, except pea .....            | 0.10              |

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0471; FRL-8151-5]

**Bifenthrin; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of bifenthrin in or on mayhaw; vegetable, root, subgroup 1B except sugar beet and garden beet; beet, garden, roots; beet, garden, tops; radish, tops; soybean, seed; soybean, hulls; soybean, refined oil; groundcherry; pepino; peanut; pistachio; and grain, aspirated fractions. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective October 24, 2007. Objections and requests for hearings must be received on or before December 24, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0471. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert

the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: [brothers.shaja@epa.gov](mailto:brothers.shaja@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

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

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

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

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the FFDCA, 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-2007-0471 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before December 24, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2007-0471, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental

Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## II. Petition for Tolerance

In the **Federal Register** of August 1, 2007 (72 FR 42074) (FRL-8140-4), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP) (6E7125, 6E7126, 6E7127, and 6E7128) by IR-4, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petitions requested that 40 CFR 180.442 be amended by establishing tolerances for residues of the insecticide bifenthrin, (2-methyl [1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate, in or on pistachio at 0.05 parts per million (ppm) (PP 6E7127); mayhaw at 1.4 ppm (PP 6E7125); vegetables, fruiting, group 8 at 0.5 ppm (PP 6E7128); peanut at 0.05 ppm (PP 6E7127); soybean, seed at 0.2 ppm (PP 6E7128); vegetable, root, except sugar beet and garden beet, subgroup 1B at 0.07 ppm (PP 6E7126); beet, garden, roots at 0.45 ppm (PP 6E7126); and beet, garden, tops at 15 ppm (PP 6E7126). That notice referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised commodity definitions and/or tolerances for vegetable, root, except sugar beet and garden beet, subgroup 1B; soybean, hulls; soybean, refined oil; and vegetable, fruiting, group 8. The reason for these changes is explained in Unit IV.C.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the 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 the 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...." These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of the FFDCA, and the factors specified in section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of bifenthrin on mayhaw at 1.4 ppm; vegetable, root, subgroup 1B except sugar beet and garden beet at 0.10 ppm; beet, garden, roots at 0.45 ppm; beet, garden, tops at 15 ppm; radish, tops at 4.5 ppm; soybean, seed at 0.2 ppm; soybean, hulls at 0.50 ppm; soybean, refined oil at 0.30 ppm; groundcherry at 0.5 ppm; pepino at 0.5 ppm; peanut at 0.05 ppm; pistachio at 0.05 ppm; and grain, aspirated fractions at 70 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

### 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. Specific information on the studies received and the nature of the adverse effects caused by bifenthrin 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>. The referenced studies are available in the Bifenthrin Human Health Risk Assessment on pages 52-54 in docket ID number EPA-HQ-OPP-2007-0471.

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern

(LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for bifenthrin used for human risk assessment can be found at <http://www.regulations.gov> in the Bifenthrin Human Health Risk Assessment on pages 27-28 in docket ID number EPA-HQ-OPP-2007-0471.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bifenthrin, EPA considered exposure under the petitioned-for tolerances as well as all existing bifenthrin tolerances in (40 CFR 180.442). EPA assessed dietary exposures from bifenthrin 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.

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 conducted a Tier 3, acute probabilistic dietary exposure and risk assessment for all supported (and pending) food uses. Anticipated residues (ARs) were developed based on the latest USDA's Pesticide Data Program (PDP) monitoring data 1998–2005, Food and Drug Administration (FDA) data, or field trial data for bifenthrin. ARs were further refined using percent crop treated (%CT) data and processing factors where appropriate.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, a refined chronic dietary exposure assessment was conducted for all the supported (and pending) food uses of bifenthrin using single point estimates of anticipated bifenthrin residues field trials. ARs were further refined using %CT data for some food commodities.

iii. *Cancer.* Bifenthrin was classified as a group "C" (possible human carcinogen). The Agency concluded that the chronic risk and exposure assessment, making use of the cPAD, to be protective of any potential carcinogenic risk. Therefore, no separate exposure assessment was conducted pertaining to cancer risk.

iv. *Anticipated residue and %CT information.* Section 408(b)(2)(E) of the FFDCAs 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 pursuant to section 408(f)(1) of the FFDCAs require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by section 408(b)(2)(E) of the FFDCAs and authorized under section 408(f)(1) of the FFDCAs. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance. Section 408(b)(2)(F) of the FFDCAs states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

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 such pesticide residue.

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

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 FFDCAs section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information for chronic dietary exposures as follows: Raspberries 70%; honeydew melon 55%; hops 35%; Brussel sprouts 1%; blackberries 20%; cantaloupes 20%; sweet corn 20%; cabbage 15%; artichokes 10%; broccoli 1%; cauliflower 5%; corn 1%; cucumbers 5%; grapes 1%; citrus 1%; lettuce 1%; peas, green 5%; pears 1%; peppers 5%; pumpkins 15%; spinach 1%; tomatoes 5%; watermelons 5%; tree nuts 1%; squash 5%; beans, green 30%; strawberries 15%; cotton 1%; and lettuce 1%. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of 5% except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five percent. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

The Agency believes that the conditions listed in Unit III.C.1.iv.a., b., and c.; 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 information on the regional consumption of food to which bifenthrin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for bifenthrin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of bifenthrin. 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>.

The environmental fate database for bifenthrin is considered adequate for the characterization of drinking water exposure. The submitted data indicate that bifenthrin is relatively persistent under both laboratory and field conditions. Bifenthrin is relatively immobile in four soils tested. Due to its low mobility, bifenthrin is not likely to reach subsurface soil environments (lower microbial activity) or ground waters. Various terrestrial field dissipation studies confirm that bifenthrin remains mostly in the upper soil level. Due to its low solubility and high level of binding it appears that bifenthrin would remain bound to the soils during run-off events and it may reach surface waters if the run-off event is accompanied by erosion. The drinking water estimates are based on an application to lettuce at the highest application rate.

Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of bifenthrin for acute and chronic exposures are estimated to be 0.0140 parts per billion (ppb) for surface water. The EECs for acute and chronic exposures are estimated to be 0.003 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessments, the water concentration value of 0.0140 ppb (lettuce-highest application rate (0.5 lb ai/A/season) 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).

Bifenthrin is currently registered for the following residential non-dietary sites: Indoor and outdoor residential non-dietary sites. Adults are potentially exposed to bifenthrin residues during residential application of bifenthrin. Adults and children are potentially exposed to bifenthrin residues after application (post-application) of bifenthrin products in residential settings. Exposure estimates were generated for residential handlers and individuals potential post-application contact with lawn, soil, and treated indoor surfaces using the EPA's Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessment, and dissipation data from a turf transferable residue (TTR) study. These estimates are considered conservative, but appropriate, since the study data were generated at maximum application rates. Short- to intermediate-term dermal and inhalation exposures may occur for residential handlers of bifenthrin products. Although residential handler risks from inhalation exposures to bifenthrin vapor are considered unlikely since the vapor pressure of bifenthrin is low, inhalation exposure was assessed during residential mixing, loading, and application of granular products. Adults and children may be potentially exposed to bifenthrin residues after application of bifenthrin products in residential settings. Short-term and intermediate-term post-application dermal exposures for adults, and short-term and intermediate-term post-application dermal and incidental oral exposures for children are anticipated. Exposure estimates were generated for potential contact with lawn, soil, and treated indoor surfaces.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Bifenthrin is a member of the pyrethroid class of pesticides. EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids. Although all pyrethroids alter nerve function by

modifying the normal biochemistry and physiology of nerve membrane sodium channels, available data show that there are multiple types of sodium channels and it is currently unknown whether the pyrethroids as a class have similar effects on all channels or whether modifications of different types of sodium channels would have a cumulative effect, nor do we have a clear understanding of effects on key downstream neuronal function, e.g., nerve excitability, or how these key events interact to produce their compound specific patterns of neurotoxicity. Without such understanding, there is no basis to make a common mechanism of toxicity finding. There is ongoing research by the EPA's Office of Research and Development and pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. This research is expected to be completed by 2007. When available, the Agency will consider this research and make a determination of common mechanism as a basis for assessing cumulative risk. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408 of the FFDCFA provides that EPA shall apply an additional ("10X") tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* EPA concluded there is not a concern for prenatal and/or postnatal toxicity resulting from exposure to bifenthrin. There was no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to bifenthrin in developmental toxicity studies and no quantitative or qualitative evidence of increased susceptibility of neonates (as compared

to adults) to bifenthrin in a 2-generation reproduction study in rats. Further, there was no quantitative or qualitative evidence of increased susceptibility of neonates (as compared to adults) to bifenthrin in a developmental neurotoxicity study. There are no concerns or residual uncertainties for prenatal and/or postnatal toxicity following exposure to bifenthrin.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

- i. The toxicity database for bifenthrin is complete.
- ii. There is no evidence that bifenthrin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study or the developmental neurotoxicity study.
- iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on anticipated residues and percent crop treated. These assumptions are based on reliable data and will not underestimate the exposure and risk. Conservative ground and surface water modeling estimates were used. Similarly conservative Residential SOPs were used to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by bifenthrin.

#### *E. Aggregate Risks and Determination of Safety*

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to bifenthrin will occupy 25% of the aPAD for the population group all infants < 1 year old, the highest estimated acute risk receiving the greatest exposure. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to bifenthrin from food and water will utilize 53% of the cPAD for the population group children 3–5 years old, the highest estimated chronic risk. Based on the use pattern, chronic residential exposure to residues of bifenthrin is not expected. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term and intermediate-term risks.* Short-term and intermediate-term aggregate exposures take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Bifenthrin is currently registered for uses that could result in short-term and intermediate-term residential exposures and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term and intermediate-term exposures for bifenthrin.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 220 for the U.S. general population, 270 for all infants <1 year old, and 150 for children 3–5 years old, the subpopulation at greatest exposure. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food, water and residential uses. Therefore, EPA does not expect short and intermediate-term aggregate exposures to exceed the Agency's LOC.

4. *Aggregate cancer risk for U.S. population.* The Agency considers the chronic aggregate risk assessment, making use of the cPAD, to be protective of any aggregate cancer risk. See Unit III.E.2.

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

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC)/electron-capture detection (ECD) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

There are no Codex MRLs for the tolerances being requested in the current petition.

##### C. Explanation of Tolerance Revisions

1. *Vegetable, fruiting, group 8.* Tolerances are established for residues of bifenthrin *per se* at 0.05 ppm in/on eggplant, at 0.15 ppm in/on tomato, and at 0.5 ppm in/on bell and non-bell pepper. EPA has determined that a fruiting vegetables crop group tolerance for residues of bifenthrin *per se* is not appropriate for the following reasons: Maximum residues in eggplant are more than a factor of five lower than the tolerance for tomatoes and the use pattern for tomato and tomatillo are different from the other members of the crop group in terms of the PHI, maximum seasonal use rate, number of applications, and interval between applications. However, EPA is establishing tolerances for residues in/on groundcherry and pepino at 0.50 ppm based on the 0.5 ppm tolerance for bell and non-bell pepper. As 40 CFR 180.1 indicates that a tolerance for residues in/on tomato applies to tomatillo, a tolerance for residues in/on tomatillo is not required.

2. *Vegetable, root, except sugar beet and garden beet, subgroup 1B.* Carrot and radish are the representative commodities of the root vegetables, except sugar beet, crop subgroup (1B). The petitioner has proposed tolerances for residues of bifenthrin in/on root vegetables, except sugar beet, crop subgroup (1B) at 0.07 ppm. Residues of bifenthrin ranged from <0.05 to 0.07 ppm in radish roots with 4 of 6 trials showing residues levels less than the LOQ (<0.05 ppm). Residues of bifenthrin were less than the LOQ (<0.05 ppm) in/on carrots from all of the submitted trials (10 trials). Based upon the submitted data, EPA concludes a tolerance for residues of bifenthrin *per se* in/on root vegetables, except sugar beet and garden beet, crop subgroup (1B) at 0.10 ppm is appropriate.

3. *Radish, tops.* Although not proposed in the **Federal Register**, based upon the submitted data, HED concludes that a separate tolerance for residues of bifenthrin *per se* in radish, tops at 4.5 ppm is appropriate.

4. *Soybean, hulls and refined oil.* The highest-average field trial (HAFT) value for residues of bifenthrin in/on soybean, seed is 0.18 ppm. The processing factors for soybean, seeds to hulls, meal, refined oil, and AGF are as follows:

- Soybean, seed hulls: 0.18 ppm x 2.6 = 0.47 ppm.
- Soybean, seed meal: No concentration of residues.

- Soybean, seed refined oil: 0.18 ppm x 1.6 = 0.29 ppm.
- Soybean, seed grain, aspirated fractions: 0.18 ppm x 380 = 68.4 ppm.

Therefore, EPA concludes that tolerances should be established for residues of bifenthrin in/on soybean, seed hulls at 0.50 ppm, soybean, seed refined oil at 0.30 ppm and grain, aspirated fractions at 70 ppm.

#### V. Conclusion

Therefore, the tolerances are established for residues of bifenthrin in or on mayhaw at 1.4 ppm; vegetable, root, subgroup 1B except sugar beet and garden beet at 0.10 ppm; beet, garden, roots at 0.45 ppm; beet, garden, tops at 15 ppm; radish, tops at 4.5 ppm; soybean, seed at 0.2 ppm; soybean, hulls at 0.50 ppm; soybean, refined oil at 0.30 ppm; groundcherry at 0.5 ppm; pepino at 0.5 ppm; peanut at 0.05 ppm; pistachio at 0.05 ppm; and grain, aspirated fractions at 70 ppm.

#### VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes,

nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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

**VII. Congressional Review Act**

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

**List of Subjects in 40 CFR Part 180**

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

Dated: October 10, 2007.

**Donald R. Stubbs,**

*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. Section 180.442 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

**§ 180.442 Bifenthrin; tolerances for residues.**

(a) *General.* \* \* \* (1) \* \* \*

| Commodity   | Parts per million |
|---|-------------------|
| * * *   | * *               |
| Beet, garden, roots .....                                       | 0.45              |
| Beet, garden, tops .....  | 15                |
| * * *   | * *               |
| Grain, aspirated fractions                                      | 70                |
| * * *   | * *               |
| Groundcherry .....  | 0.5               |
| * * *   | * *               |
| Mayhaw .....  | 1.4               |
| * * *   | * *               |
| Peanut .....  | 0.05              |
| * * *   | * *               |
| Pepino .....  | 0.5               |
| * * *   | * *               |
| Pistachio .....   | 0.05              |
| * * *   | * *               |
| Radish, tops .....  | 4.5               |
| * * *   | * *               |
| Soybean, hulls .....  | 0.50              |
| Soybean, refined oil .....                                      | 0.30              |
| Soybean, seed .....   | 0.2               |
| * * *   | * *               |
| Vegetable, root, sub-group 1B except sugar beet and garden beet | 0.10              |
| * * *   | * *               |

\* \* \* \* \*  
 [FR Doc. E7-20753 Filed 10-23-07; 8:45 am]  
**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0848; FRL-8152-9]

**Fenamidone; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fenamidone in or on carrot; sunflower; Brassica, head and stem, subgroup 5A; Brassica, leafy greens, subgroup 5B; vegetable, fruiting, group 8, except nonbell pepper; pepper, nonbell; vegetable, leafy, except Brassica, group 4; cotton, gin byproducts; cotton, undelinted seed; and combined residues of fenamidone

and its metabolite RPA 717879 in or on strawberry. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective October 24, 2007. Objections and requests for hearings must be received on or before December 24, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0848. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: [brothers.shaja@epa.gov](mailto:brothers.shaja@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

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