

calculated as flutolanil, in or on the following commodities:

Commodity	Parts per million
Soybean, forage	8.0
Soybean, hay	2.5
Soybean, seed	0.20
Wheat, bran	0.20
Wheat, forage	2.5
Wheat, grain	0.05
Wheat, hay	1.2
Wheat, straw	0.20

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0535; FRL-8366-4]

Bifenthrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes 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 food commodities bushberry subgroup 13-07B; and leafy petioles subgroup 4B. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this action revises previously established time-limited tolerances for residues of bifenthrin in or on orchardgrass, forage and orchardgrass, hay in response to the approval of a specific exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing the use of this insecticide on orchardgrass in the State of Oregon to control western orchardgrass billbug. Residue data have been submitted indicating the need to increase the tolerances from their original level. This regulation establishes maximum permissible levels of residues of bifenthrin in these food/feed commodities. The time-limited tolerances expire and are revoked on December 31, 2009.

DATES: This regulation is effective June 11, 2008. Objections and requests for hearings must be received on or before August 11, 2008, 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-2007-0535. 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 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 www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are

not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

In addition to accessing 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 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-2007-0535. 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 August 11, 2008.

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-2007-0535, 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 FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7227) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition 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 food commodities bushberry subgroup 13-B and junberry; lingonberry; salal; aronia berry; blueberry, lowbush; buffalo currant; Chilean guava; European barberry; highbush cranberry; honeysuckle; jostaberry; native currant; sea buckthorn at 2.0 ppm; and leafy petioles subgroup 4-B at 3.0 ppm. 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 corrected the commodity definition and utilized established new crop groups/subgroups outlined in the final rule for Pesticide Tolerance Crop Grouping Program dated December 7, 2007 (72 FR 69150) (FRL-8343-1). The new commodity definition, Bushberry subgroup 13-07B, includes all proposed commodities as well as additional related commodities. Therefore, a separate tolerance for each commodity is not needed. Based on supporting data, EPA also revised the proposed tolerance level from 2.0 to 1.8 ppm. The reasons for these changes are explained in Unit IV.C.

EPA is also revising previously established time-limited tolerances for residues of the insecticide bifenthrin in or on orchardgrass, forage at 2.5 ppm and orchardgrass, hay at 4.5 ppm. These tolerances expire and are revoked on December 31, 2009. The Agency is establishing these time-limited tolerances in response to a specific emergency exemption request under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. 136p, on behalf of the Oregon Department of Agriculture for the emergency use of bifenthrin on orchardgrass grown for seed, to control the orchardgrass billbug.

Oregon produces nearly all of the nation's orchardgrass seed, which is primarily used as a high protein pasture grass. The key pest of orchardgrass in Oregon is the orchardgrass billbug, which lays eggs into the stem where they hatch and are hard to control by insecticides. The effect of drought conditions in fields serves to magnify damage and loss associated with this pest. Significant yield losses, and subsequently economic losses, are expected without adequate control. EPA has authorized under FIFRA section 18 the use of bifenthrin on orchardgrass for control of orchardgrass billbug in Oregon. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of the emergency exemption request, EPA assessed the potential risks presented by the residues of bifenthrin in or on orchardgrass, forage and orchardgrass, hay. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary time-limited tolerances under section 408(1)(6) of the FFDCA would be consistent with the safety standard

and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address the urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is revising these time-limited tolerances without notice and opportunity for public comment as provided in section 408 (1) (6) of the FFDCA. Although, these time-limited tolerances expire and are revoked on December 31, 2009, under section 408 (1) (5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on orchardgrass, forage and hay after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed levels that were authorized by these time-limited tolerances at the time of application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data, or other relevant information on this pesticide indicates that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether bifenthrin meets EPA's registration requirements for use on orchardgrass, forage and hay, or whether a permanent tolerance for these uses would be appropriate. Under this circumstance, EPA does not believe that the time-limited tolerance serves as a basis for registration of bifenthrin by a State for special local needs under FIFRA section 24(c). Nor does the time-limited tolerance serve as the basis for any State other than Oregon to use this pesticide on these commodities under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166.

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....” These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of 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 food commodities bushberry subgroup 13-07B at 1.8 ppm; leafy petioles subgroup 4-B at 3.0 ppm as well as the time-limited tolerance for residues of bifenthrin in or on orchardgrass, forage at 2.5 ppm and orchardgrass, hay at 4.5 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by 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> in document entitled “Human Health Risk Assessment” in docket ID number EPA-HQ-OPP-2007-0535-0004.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified

(the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for bifenthrin used for human risk assessment can be found at <http://www.regulations.gov> in the Bifenthrin Human Health Risk Assessment in docket ID number EPA-HQ-OPP-2007-0535-0004.

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 United States 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 highly-refined, acute probabilistic dietary exposure and risk assessment for all registered 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 the latest percent crop-treated (PCT) data and processing factors where appropriate. For new uses and uses that have been registered less than five years 100 PCT was assumed.

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 registered and pending food uses of bifenthrin using single point estimates of anticipated bifenthrin residues, including PCT for registered food/feed commodities. For new uses and uses that have been registered less than 5 years, 100 PCT was assumed.

iii. *Cancer.* There was no conclusive evidence of carcinogenic potential of bifenthrin in the rat. A mouse oncogenicity study provided some evidence for carcinogenic potential in this species. In the mouse oncogenicity study, high-dose (81.3 mg/kg/day) males showed a highly significant increased incidence of urinary bladder tumors. Other findings in the mouse study included a dose-related trend of increased combined incidences of adenoma and adenocarcinoma of the liver (males only), and increased incidences of bronchioalveolar adenomas and adenocarcinomas of the lung in females at some, but not all dose levels relative to their controls. The EPA has characterized bifenthrin as Category C (possible human carcinogen) primarily on the basis of a mouse study. For the purpose of risk characterization, the reference-dose (RfD) approach should be used for quantification of human cancer risk.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of the 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 pursuant to section 408(f)(1) of the FFDCA 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 FFDCA and authorized under section 408(f)(1) of the FFDCA. 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 FFDCA 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 the 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 areas.

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 used PCT information for chronic dietary exposure as follows:

Raspberries 70%; honeydew melon 55%; hops 35%; alfalfa 1%; blackberries 20%; cantaloupes 20%; sweet corn 20%; cabbage 15%; artichokes 10%; broccoli 1%; cauliflower 5%; corn 1%; cucumbers 5%; grapes 1%; canola/rapeseed 5%; lettuce 1%; peas, green 5%; carrots 5%; peppers 5%; pumpkins 15%; dry beans/peas 1%; tomatoes 5%; watermelons 5%; onions 1%; peanuts 1%; pecans 1%; potatoes 1%; soybean 1%; squash 5%; sweet potatoes 35%; beans, green 30%; strawberries 15%; cotton 1%; and lettuce 1%.

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 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 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 for drinking water concentrations, the Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for bifenthrin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of bifenthrin for acute and chronic exposure were calculated based on a maximum application rate of 0.5 pound(lb) active ingredient(ai)/acre(A)/season. For both acute and chronic exposures, the EDWC in surface water was estimated as 0.0140 ppb. The

EDWC for both acute and chronic exposures is estimated to be 0.0030 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 (based on the maximum applied rate to lettuce at 0.5 lb a.i./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. Both 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. Short-term and intermediate-term dermal and inhalation exposures for adults, and short-term and intermediate-term dermal and incidental oral exposures for children are anticipated. These estimates are considered conservative, but appropriate, since the study data were generated at maximum application rates.

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."

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. When available, the Agency will evaluate results of 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(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 FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* 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. Additionally, 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 the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for bifenthrin is complete.
- ii. A DNT study with bifenthrin is available. This study does not show any evidence of increased susceptibility of offspring following exposure to bifenthrin. This study did not impact endpoints selected by the Agency for various exposure scenarios.
- iii. 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.
- iv. 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. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to bifenthrin in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of 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

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

1. *Acute risk.* 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 all infants (<1 year old) the population group 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 chronic exposure to bifenthrin from food and water will utilize 55% of the cPAD for children 3–5 years old the population group receiving the greatest exposure. 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- and Intermediate-term risks.* Short-term and intermediate-term aggregate exposure takes into account short-term 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 exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water and short-term and intermediate-term exposures to bifenthrin.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded 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 180 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.C.iii.

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)) are available to enforce the tolerance expression. The limit of quantitation (LOQ) for these

methods is 0.05 ppm. 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.

B. International Residue Limits

There are no Codex, Canadian, or Mexican MRLs for bifenthrin in or on the proposed commodities.

C. Revisions to Petitioned-For Tolerances

Based on evaluation of available data supporting this petition, the Agency revised the registrant's proposed tolerances for Bushberry, subgroup 13B, including proposed individual berries tolerance, from 2.0 to 1.8 ppm and applied the corrected commodity definition, Bushberry subgroup 13-07B. Separate tolerances for new commodities listed in crop subgroup 13-07B are not required as outlined in the Pesticide Tolerance Crop Grouping Program Final Rule published in the **Federal Register** of December 7, 2007 (72 FR 69150) (FRL-8340-6).

The Agency determined that adequate data are available to support establishing a tolerance for the bushberry subgroup 13-07B. IR-4 petitioned for a tolerance for bushberry subgroup 13B as well as an individual tolerance on juneberry; lingonberry; salal; aronia berry; blueberry, lowbush; buffalo currant; Chilean guava; European barberry; highbush cranberry; honeysuckle; jostaberry; native currant; sea buckthorn (PP 7E7227). EPA has expanded and revised berries group 13. Changes to crop group 13 (berries) included adding new commodities, revising existing subgroups and creating new subgroups (including a bushberry subgroup 13-07B consisting of the commodities requested in PP 7E7227 and cultivars, varieties, and/or hybrids of these).

EPA indicated in the December 7, 2007 final rule as well as the earlier May 23, 2007 proposed rule (72 FR 28920) that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing tolerances on Bushberry subgroup 13-07B. Bushberry subgroup 13-07B consists of the berries for which tolerances were requested in PP 7E7227, as well as, additional commodities not included in the original tolerance petition.

EPA concludes it is reasonable to revise the petitioned-for tolerances so

that they agree with the recent crop grouping revisions because:

i. Although the subgroup includes several new commodities, these commodities were proposed as individual tolerances and are closely related minor crops which contribute little to overall dietary or aggregate exposure and risk;

ii. Bifenthrin exposure from these added commodities was considered when EPA conducted the dietary and aggregate risk assessments supporting this action; and

iii. the representative commodities for the revised subgroup have not changed.

Bushberry subgroup 13-07B. The field trials with bifenthrin on blueberries, representative crop, are adequate. An adequate number of trials were conducted reflecting the proposed use patterns in the appropriate geographic regions, and the appropriate commodities were collected at the proposed "pre" harvest intervals (PHIs). Samples were analyzed using adequate and appropriate analytical methods. Tolerance levels for residues in or on bushberry (subgroup 13-07B) were determined using the North American Free Trade Agreement (NAFTA) maximum residue levels (MRL)/Tolerance Harmonization Spreadsheet.

V. Conclusion

Therefore, tolerances are established 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 food commodities bushberry subgroup 13-07B at 1.8 ppm; and leafy petioles subgroup 4B at 3.0 ppm. In addition, this regulation revises the time-limited tolerances for residues of bifenthrin in or on orchardgrass, forage at 2.5 ppm and orchardgrass, hay at 4.5 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety*

Risks (62 FR 19885, April 23, 1997).

This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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

VII. Congressional Review Act

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

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

List of Subjects in 40 CFR Part 180

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

Dated: May 28, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.442 is amended by alphabetically adding the following commodities to the table in paragraph (a) and by revising paragraph (b) to read as follows:

§180.442 Bifenthrin; tolerances for residues.

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

Commodity	Parts per million
* * *	* *
Bushberry subgroup 13-07B	1.8

Commodity	Parts per million
* * *	* *
Leafy petioles subgroup 4B	3.0
* * *	* *

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for the 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 connection with use of the pesticide under a section 18 emergency exemption granted by EPA. This tolerance will expire and is revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Orchardgrass, forage	2.5	12/31/09
Orchardgrass, hay	4.5	12/31/09

* * * * *

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