Commodity	Parts Per Million
Sugar apple	0.30
Sunflower, seed	0.05
Tomato, paste	6.0
Tomato, pomace (wet or dried)	4.O
Tomato, puree	3.0
Vegetable, brassica leafy, group 5	3.5
Vegetable, cucurbit, group 9	0.5
Vegetable, fruiting, group 8	1.0
Vegetable, leaves of root and tuber, group 2	4.0
Vegetable, legume, except soybean, group 6	4.0
Vegetable, root and tuber, group 1, except sugar beet	0.40
Watercress	3.5
Watercress, upland	3.5
Wax jambu	1.0
Wheat, forage	7.0
Wheat, grain	0.05
Wheat, hay	0.5
Wheat, straw	0.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent combined residues of the insecticide imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, when present therein as a result of the application of the pesticide to growing crops listed in this section and other non-food crops as follows:

Commodity	Parts Per Million
Forage, fodder, and straw of Grain, cereal crop group (forage)	2.0
Forage, fodder, and straw of Grain, cereal crop group (hay)	6.0
Forage, fodder, and straw of Grain, cereal crop group (stover)	0.3
Forage, fodder, and straw of Grain, cereal crop group (straw)	3.0
Grain, cereal, group 15	0.05
Sweet corn, kernel plus cob with husks removed	0.05
Vegetable, foliage of legume, group 7	2.5
Vegetable, legume, crop group 6	0.3

[FR Doc. E6–13092 Filed 8–10–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0366; FRL–8081–7]

Bifenthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bifenthrin in or on Vegetable, tuberous and corm, subgroup 1C; Brassica, leafy greens, subgroup 5B; turnip, greens; Pea and bean, dried shelled, except soybean, subgroup 6C; coriander, leaves; coriander, dried leaves; coriander, seed and okra. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). EPA is also deleting an existing time-limited bifenthrin tolerance that is no longer needed as a result of this action.

DATES: This regulation is effective August 11, 2006. Objections and requests for hearings must be received on or before October 10, 2006, 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–2006–0366. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 provides 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 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, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA

procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0366 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 on or before October 10, 2006.

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 your copies, identified by docket ID number EPA–HQ–OPP–2006–0366, 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 Building), 2777 S. Crystal Drive, 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 telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of May 10, 2006 (71 FR 27246) (FRL–8067–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP) 2E6451, 3E6882, 2E6492, 2E6423, and 4E6843 by Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. 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 leafy brassica greens, subgroup 5B at 3.0 parts per million (ppm) and turnip greens at 3.0 ppm (2E6451); tuberous and corm vegetables, subgroup 1C at 0.1 ppm (3E2688); okra at 0.5 ppm (2E6492); dried shelled pea and bean (except soybean), subgroup 6C at 0.1 ppm (2E6423); and cilantro at 5.0 ppm (4E6843). That notice included a summary of the petition prepared by FMC, the registrant. There were no comments received in response to the notice of filing. The proposed tolerances were later amended as follows: Vegetable, tuberous and corm, subgroup 1C at 0.05 ppm (3E2688); Brassica, leafy greens, subgroup 5B at 3.5 ppm and turnip, greens at 3.5 ppm (2E6451); Pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm, coriander, leaves at 6.0 ppm, coriander, dried leaves at 25 ppm, and coriander, seed at 5.0 ppm (4E6843); okra at 0.5 ppm (2E6492). EPA is also deleting an established tolerance in 40 CFR 180.442(b) that is no longer needed, as a result of this action. The tolerance deletion under 40 CFR 180.442(b) is a time-limited tolerance established under section 18 emergency exemptions that is superceded by the establishment of a general tolerance for bifenthrin section 40 CFR 180.442(a). The revision to 40 CFR 180.442 is as follows: Delete the time-limited tolerance for sweet potato, roots at 0.05 ppm under 40 CFR 180.442(b). The tolerance for vegetable, tuberous and corm, subgroup 1C at 0.05 ppm that is being established includes sweet potato.

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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of bifenthrin (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate on Brassica, leafy greens, subgroup 5B at 3.5 ppm; coriander, dried leaves at 25 ppm; coriander, leaves at 6.0 ppm; coriander, seed at 5.0 ppm; okra at 0.50 ppm; Pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm; turnip, greens at 3.5 ppm; and Vegetable, tuberous and corm, subgroup 1C at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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. Specific information on the studies received and the nature of the toxic effects caused by bifenthrin as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effectlevel (LOAEL) from the toxicity studies can be found at *http://www.epa.gov/fedrgstr/EPA-PEST/2003/April/Day-30/p10400.htm*.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for bifenthrin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 30, 2003 (68 FR 23056) (FRL–7304–4).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.442) for the residues of bifenthrin (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on a variety of raw agricultural commodities. In addition, tolerances for livestock commodities have been established for the residues of bifenthrin (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on egg; milk fat; meat, fat, and meat byproducts (mbyp) of cattle, goat, hog, horse, poultry and sheep. Risk assessments were conducted by EPA to assess 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.

The Dietary Exposure Evaluation Model (DEEM-FCID(™), Version 2.03) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A Tier 3, acute probabilistic dietary exposure assessment was conducted for all registered and pending food uses and drinking water. Anticipated residues (ARs) were developed based on 1998–2003 USDA's Pesticide Data Program (PDP) monitoring data, Food and Drug Administration (FDA) data, or field trial data for bifenthrin. ARs were further refined using percent crop treated (PCT) data and processing factors where appropriate.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID(™), Version 2.03), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A dietary exposure assessment was conducted for all registered and pending food uses and drinking water. Anticipated residues (ARs) were developed based on 1998–2003 USDA's Pesticide Data Program (PDP) monitoring data, Food and Drug Administration (FDA) data, or field trial data for bifenthrin. ARs were further refined using percent crop treated (PCT) data and processing factors where appropriate.

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 percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins 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 the Agency can make the following findings: Condition 1, that 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if 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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Artichokes at 10%, Blackberries at 20%, Broccoli at 1%, Cabbage at 10%, Cantaloupe at 15%, Cauliflower at 1%, Corn at 15%, Sweet corn at 15%, Cucumber at 5%, Brussel Sprouts at 1%, Dried Beans at 9%, Dried Peas at 9%, Grapes at 1%, Orange at 1%, Lettuce at 1%, Sweet peas at 5%, Pears at 1%, Nonbell Peppers at 5%, Potatoes at 39%, Honeydew melon at 55%, Pumpkin and squash at <15%, Raspberry at 65%, Spinach at 1%, Tomato at 5%, Watermelon at 5%, Nuts (almonds, pecan, and walnuts) at 1%, Hops at 63%, Green Beans at 25%, Sweet Bell Pepper at 5%, Okra at 47%, Strawberry at 15%, Cotton at <1%, Sorghum < at 1%, and Soybeans at <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 five percent 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 United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent 6 years.

EPA estimates projected percent crop treated (PPCT) for a new pesticide use by assuming that the PCT during the pesticide's initial 5 years of use on a specific use site will not exceed the average PCT of the market leader (i.e., the one with the greatest PCT) on that site over the three most recent surveys. Comparisons are only made among pesticides of the same pesticide types (i.e., the dominant miticide on the use site is selected for comparison with the new miticide). The PCTs included in the average may be each for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year selected. Typically, EPA uses USDA/NASS as the source for the PCT data because they are publicly available. When a specific use site is not surveyed by USDA/NASS, EPA uses proprietary data and calculates the estimated PCT.

This estimated PPCT, based on the average PCT of the market leader, is appropriate for use in the chronic dietary risk assessment. This method of estimating a PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use. The predominant factors that generally can be analyzed based on readily available information and that bear on whether the estimated PPCT could be exceeded are whether there are concerns with pest pressures as indicated in emergency exemption requests or other readily available information, whether the new pesticide controls a broader spectrum of pests than the dominant pesticide(s) and/or whether the new pesticide has a shorter pre-harvest interval (PHI).

All such relevant information currently available has been considered for bifenthrin on dry beans/peas, potatoes and okra, and it is unlikely that actual PCT for bifenthrin will exceed the estimated PPCT for bifenthrin on each of these three crops during the next five years mainly because of the relatively longer PHI of bifenthrin relative to each of the respective leading insecticides.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure 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 physical 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 and Screening Concentrations in Groundwater models, the estimated environmental concentrations (EECs) of bifenthrin for acute exposures are estimated to be 0.014 parts per billion (ppb) for surface water and 0.00300 ppb for ground water. The EECs for chronic exposures are estimated to be 0.0140 ppb for surface water and 0.00300 ppb for ground water.

The estimated drinking water concentrations (EDWCs) for bifenthrin were calculated based on a maximum application rate of 0.5 lb ai/A/season. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID(™), Version 2.03). For acute dietary risk assessment, the peak water concentration value of 0.0140 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the annual average concentration of 0.0140 ppb was used to access 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 both 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 handler exposures, and potential post-application contact with lawn, soil, and treated indoor surfaces using the EPA's Draft Standard Operating Proceedures (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.

The risk assessment was conducted using the following residential exposure assumptions: 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 gas/vapor are considered unlikely, since the vapor pressure of bifenthrin is low, inhalation exposure was assessed for aerosols/particulates 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- and intermediate-term post-application dermal exposures for adults, and short- 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*. 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. 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 FFDCA provides that EPA shall apply an additional 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. 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 safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* EPA concluded that 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. In addition, there are no concerns or residual uncertainties for prenatal and/or postnatal toxicity following exposure to bifenthrin.

3. *Conclusion.* EPA has concluded that in light of the lack of the developmental neurotoxicity (DNT) study the acute RfD, based on the no observed adverse effect level (NOAEL) of 32.8 milligrams/kilograms/day (mg/kg/day) be divided by an uncertainty factor (UF) of 1,000 (10X for interspecies extrapolation, 10X for intraspecies variations, and a 10X FQPA factor for an incomplete database for lack of a DNT study). EPA has concluded that, based on reliable data, an additional FQPA factor of 3X in the form of a database uncertainty factor is required for all repeated-dose exposure scenarios to address the lack of a developmental neurotoxicity study (DNT) because existing data indicate that the results of the DNT study might impact the current toxicology endpoint selection and RfDs. Further explanation for the choice of 3X is provided in Unit III.D. of the final rule published in the **Federal Register** of April 30, 2003 (68 FR 23056) (FRL–7304–4). An UFDB of 10X is applied to single dose exposure scenarios (i.e., acute RfD) to account for the lack of the DNT. Acceptable developmental studies in the rat and rabbit revealed no increased susceptibility of rat or rabbit fetuses following *in utero* exposure to bifenthrin. In addition, there was no evidence of increased susceptibility of young rats in the reproduction study with bifenthrin. There are no residual uncertainties in the exposure databases. The dietary food exposure assessment were refined using percent crop treated (CT) information, and anticipated residue (AR) values calculated from the available monitoring data and field trial results. Dietary drinking water exposure is based on conservative modeling estimates, and the Agency's Residential standard operating procedures (SOPs), in conjunction with some chemical specific data, were used to assess residential handler and post-application exposure to adults and children. These assessments will not underestimate the exposure and risks posed by bifenthrin.

E. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated drinking water concentrations (EDWCs). The DWLOC values are not regulatory standards for drinking water, but are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. More information on the use of DWLOCs in dietary aggregate risk assessments can be found at *http://www.epa.gov/oppfead1/trac/science/screeningsop.pdf.* More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface and ground water EDWCs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and drinking water to bifenthrin will occupy 24% of the aPAD for the U.S. population, 18% of the aPAD for females 13 years and older, 38% of the aPAD for all infants less than 1 year old, and 43% of the aPAD for children 3-5 years old, the subpopulation at 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 drinking will utilize 10% of the cPAD for the U.S. population, 12% of the cPAD for All infants less than 1 year old, and 26% of the cPAD for children 1-2 years old, the subpopulation at greatest exposure. Based 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 risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

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

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water and residential exposures aggregated result in aggregate MOEs of 530 for the general U.S. population, 380 for all infants less than 1 year old, and 350 for children 1-2 years old the subpopulation at greatest exposure. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food, water and residential uses. Therefore, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern.

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

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

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food, water and residential exposures aggregated result in aggregate MOEs of 530 for the general U.S. population, 380 for all infants less than 1 year old, and 350 for children 1-2 years old the subpopulation at greatest exposure. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food, water, and residential uses. Therefore, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern.

5. *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.

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, and 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 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

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for residues of bifenthrin in/on various commodities. Codex MRLs are expressed in terms of bifenthrin *per se*, as are U.S. tolerances. The only established Codex MRL relevant to the current petitions is for potato at 0.05 mg/kg. As the recommended tolerance of tuberous and corm vegetables is also 0.05 ppm, this tolerance is in harmony with the Codex MRL for potato. There are no equivalent Canadian or Mexican MRLs for the tolerances being requested in the current petition.

V. Conclusion

Therefore, tolerances are established for residues of bifenthrin, (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate on Brassica, leafy greens, subgroup 5B at 3.5 ppm; coriander, dried leaves at 25 ppm; coriander, leaves at 6.0 ppm; coriander, seed at 5.0 ppm; okra at 0.50 ppm; Pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm; turnip, greens at 3.5 ppm; and Vegetable, tuberous and corm, subgroup 1C at 0.05 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 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as addedby the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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:August 1, 2006.

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 commodities to the table in paragraph (a) and by removing Sweet potato, roots from the table in paragraph (b) to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * *	*
Brassica, leafy greens, subgroup 5B	3.5
* * * *	*
Coriander, dried leaves	25
Coriander, leaves	6.0
Coriander, seed	5.0
* * * *	*
Okra	0.50
Pea and bean, dried shelled, expect soybean, subgroup 6C	0.15
* * * *	*
Turnip, greens	3.5
* * * *	*
Vegetable, tuberous and corm, subgroup 1C	0.05

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[FR Doc. E6–13058 Filed 8–10–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0495; FRL–8086–1]

Sanitizers with No Food-Contact Uses in Registered Pesticide Products; Revocation of Tolerance Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking eight exemptions from the requirement of a tolerance that are associated with six food-contact surface sanitizing solutions because these specific tolerance exemptions correspond to uses no longer current or registered in the United States under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and because there are insufficient data to make the determination of safety required by the Federal Food, Drug, and Cosmetic Act (FFDCA). These ingredients are subject to reassessment by August 2006 under section 408(q) of FFDCA, as amended by the Food Quality Protection Act of 1996 (FQPA). The eight tolerance exemptions are considered ''reassessed'' for purposes of FFDCA's section 408(q) and count as a tolerance reassessment toward the August 2006 review deadline.

DATES: This rule is effective 90 days from August 11, 2006. Objections and requests for hearings must be received on or before October 10, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit V. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0495. All documents in the docket are listed in the index for the docket. 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: Laura Bailey, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: 703-308-6212; e-mail address: *bailey.laura@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- 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 provides 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. 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 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, as amended by the FQPA, any person may