

purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 30, 2012.

**Jared Blumenfeld,**

*Regional Administrator, Region IX.*

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

*Authority:* 42 U.S.C. 7401 *et seq.*

#### Subpart F—California

■ 2. Section 52.282 is amended by adding paragraph (e) to read as follows:

#### § 52.282 Control strategy and regulations: Ozone.

\* \* \* \* \*

(e) *Determinations of Attainment.* Effective November 13, 2012.

(1) *Approval of applications for extensions of applicable attainment dates.* Under section 181(a)(5) of the Clean Air Act, EPA is approving the applications submitted by the California Air Resources Board dated March 23, 2010 and May 24, 2010 for extensions of the applicable attainment date for the Mariposa and Tuolumne Counties and Nevada County 8-hour ozone nonattainment areas, respectively, from June 15, 2010 to June 15, 2011.

(2) *Determinations of attainment by the applicable attainment date.* EPA has determined that the Amador and Calaveras Counties, Chico, Kern County, Mariposa and Tuolumne Counties, Nevada County, and Sutter County 8-hour ozone nonattainment areas in

California attained the 1997 8-hour ozone national ambient air quality standard (NAAQS) by their applicable attainment dates. The applicable attainment dates are as follows: Amador and Calaveras Counties (June 15, 2010), Chico (June 15, 2007), Kern County (June 15, 2010), Mariposa and Tuolumne Counties (June 15, 2011), Nevada County (June 15, 2011), and Sutter County (June 15, 2007).

(3) *Determination of attainment.* EPA is determining that the Amador and Calaveras Counties, Chico, Kern County, Mariposa and Tuolumne Counties, Nevada County, Sutter County and Ventura County 8-hour ozone nonattainment areas have attained the 1997 8-hour ozone standard, based upon complete quality-assured data for 2009–2011. Under the provisions of EPA's ozone implementation rule (see 40 CFR 51.918), these determinations suspend the attainment demonstrations and associated reasonably available control measures, reasonable further progress plans, contingency measures, and other planning SIPs related to attainment for as long as the areas continue to attain the 1997 8-hour ozone standard. If EPA determines, after notice-and-comment rulemaking, that any of these areas no longer meets the 1997 ozone NAAQS, the corresponding determination of attainment for that area shall be withdrawn.

[FR Doc. 2012–22469 Filed 9–13–12; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA–HQ–OPP–2009–1008; FRL–9361–6]

#### Bifenthrin; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of bifenthrin in or on tea, dried; grass, forage; and grass, hay. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation additionally establishes time-limited tolerances in or on apple, nectarine, and peach under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The time-limited tolerances expire and are revoked on December 31, 2015. Finally, this regulation removes time-limited tolerances on orchardgrass, forage and

orchardgrass, hay, as they will be superseded by permanent tolerances.

**DATES:** This regulation is effective September 14, 2012. Objections and requests for hearings must be received on or before November 13, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2009–1008, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

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

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this action apply to me?

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

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

You may access a frequently updated electronic version of EPA's tolerance

regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-1008 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 13, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-1008, by one of the following methods:

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

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

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 19, 2010 (75 FR 13277) (FRL-8813-2), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7652) by IR-4, 500 College Road East, Suite 201W., 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 tea (import tolerance) at 25 parts per million (ppm); and tolerances with regional registrations in or on grass, forage at 2.5 ppm and grass, hay at 4.5 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by FMC Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

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

To control the brown marmorated stink bug, EPA is also establishing time-limited tolerances for the use of bifenthrin in or on apple, nectarine, and peach at 0.5 ppm. These tolerances expire and are revoked on December 31, 2015. The Agency is establishing the time-limited tolerances in response to an informal crisis exemption request under FIFRA section 18 on behalf of the states of Delaware, Maryland, New Jersey, North Carolina, Pennsylvania, Virginia, and West Virginia for the emergency use of bifenthrin to control the brown marmorated stink bug on these commodities.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of bifenthrin in or on apple, nectarine, and peach. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and the Agency decided that the necessary tolerances under section 408(l)(6) of 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 an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although these time-limited tolerances expire and are revoked on December 31, 2015, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on apple, nectarine, and peach after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions whether bifenthrin meets FIFRA's registration requirements for use in or on apple, nectarine, and peach, or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerances serve as a basis for registration of bifenthrin by a State for Special Local Needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for persons in any State other than those listed to use this pesticide on these crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for bifenthrin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

## 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 assessment includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires

EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.” \* \* \*

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

Bifenthrin has a low order of acute toxicity via the dermal and inhalation routes of exposure and has moderate acute toxicity via the oral route. It is neither an eye nor skin irritant, and it is not a dermal sensitizer. Behavioral changes characteristic of Type I pyrethroids, such as muscle tremors, were noted in most of the bifenthrin experimental toxicology studies, consistent with its mode of action of delaying the inactivation of voltage gated sodium channels. Additional effects seen in one or more toxicity studies for bifenthrin included muscle twitching, decreased grip strength, altered landing foot splay, depressed respiration, increased grooming counts, loss of muscle coordination, staggered gait, exaggerated hind limb flexion, and convulsions at high doses. Decreased

body weight, body weight gains and food consumption were also noted in repeat-dosing dietary studies. Evidence of increased qualitative or quantitative susceptibility of offspring was not observed in any of the available guideline toxicity studies for bifenthrin.

Bifenthrin is classified as a “possible human carcinogen” based on an increased incidence of urinary bladder tumors in mice. However, EPA concluded that the bladder tumors may not be uncommon in mice and are not likely to be malignant. Additionally, these tumors were observed only in male mice at the highest dose tested and the incidence was of borderline significance. No evidence of carcinogenicity was observed in bifenthrin carcinogenicity studies in rats, and bifenthrin was negative in five different tests for mutagenicity but was marginally active in a forward mutation test in mouse lymphoma cells. Overall, based on the available information, there is a low concern for mutagenicity. Taking into account all of this information, the Agency has determined that quantification of risk using a non-linear approach (i.e., acute population-adjusted dose (aPAD)) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to bifenthrin. While the Agency would typically use a chronic population-adjusted dose (cPAD) to protect for cancer concerns, use of the aPAD is protective for bifenthrin because increasing toxicity with increasing duration of exposure is not seen for bifenthrin. The no observed adverse effect level (NOAEL) observed in the mouse chronic study, in which tumors were observed, is 6.7 mg/kg/day, 2-fold higher than the points of departure (POD) used for acute risk assessment.

Specific information on the studies received and the nature of the adverse effects caused by bifenthrin as well as the dose at which the motor activity change is equal to one standard deviation (SD) from the control value (BMD<sub>1SD</sub>), and the lower 95% confidence limit of the BMD value (the

BMDL<sub>1SD</sub>), resulting from the benchmark data (BMD) analysis of the toxicity studies can be found at <http://www.regulations.gov> in document, “Bifenthrin: Human Health Risk Assessment to Support Section 3 New Uses for a Bed Bug Treatment, Grass Grown for Seed, Tolerances for Imported Tea, and a Section 18 Emergency Exemption Use on Apple, Nectarine, and Peach” at pages 62–70 in docket ID number EPA–HQ–OPP–2009–1008.

*B. Toxicological Points of Departure/ Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological POD and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. Typically, PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL).

Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for bifenthrin used for human risk assessment is shown in Table 1. of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BIFENTHRIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Children < 6 years old) ...	BMDL <sub>1SD</sub> = 3.1 mg/kg.  UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x mg/kg/day	Acute RfD = 0.031 mg/kg/day.  aPAD = 0.010.	Wolansky et al. (2006) BMD <sub>1SD</sub> = 4.1 mg/kg based on reductions in locomotor activity; supported by multiple guideline studies.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BIFENTHRIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/Scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
	FQPA SF = 3x		
Acute dietary (General population, including $\geq 6$ years old).	BMDL <sub>1SD</sub> = 3.1 mg/kg. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 3x	Acute RfD = 0.031 mg/kg/day.  aPAD = 0.031 mg/kg/day.	Wolansky et al. (2006) BMD <sub>1SD</sub> = 4.1 mg/kg based on reductions in locomotor activity; supported by multiple guideline studies.
Chronic dietary (All populations) .....	Because of the rapid reversibility of the most sensitive neurotoxicity endpoint used for quantifying risks, there is no increase in hazard with increasing dosing duration. Therefore, the acute dietary endpoint is protective of the endpoints from repeat dosing studies, including chronic dietary exposures.		
Incidental oral short-term (1 to 30 days)	BMDL <sub>1SD</sub> = 3.1 ..... UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 3x	Residential: < 6 years old. LOC is an MOE = 300 $\geq 6$ years old, LOC is an MOE = 100.	Wolansky et al. (2006). BMD <sub>1SD</sub> = 4.1 mg/kg based on reductions in locomotor activity; supported by multiple guideline studies.
Dermal short-term (1 to 30 days) .....	BMDL <sub>10</sub> = 96.3 mg/kg/day. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 3x	Residential: < 6 years old. LOC is an MOE = 300 $\geq 6$ years old, LOC is an MOE = 100. Occupational: Adults, LOC is an MOE = 100.	21-day dermal study in rats. BMD <sub>10</sub> = 187.0 mg/kg/day, based on exaggerated hind limb flexion.
Inhalation short-term (1 to 30 days) .....	BMDL <sub>1SD</sub> = 3.1 mg/kg. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 30x*	Residential: Adults LOC is an MOE = 1,000.	Wolansky et al. (2006). BMD <sub>1SD</sub> = 4.1 mg/kg based on reductions in locomotor activity; supported by multiple guideline studies.
Cancer (Oral, dermal, inhalation) .....	Bifenthrin has been classified as a possible human carcinogen. Because of the rapid reversibility of the most sensitive neurotoxicity endpoint used for quantifying risks, there is no increase in hazard with increasing dosing duration. Therefore, the acute dietary endpoint is protective of the endpoints from repeat dosing studies, including cancer dietary exposures.		

FQPA SF = Food Quality Protection Act Safety Factor. FQPA SF is composed of the 3X factor for increased quantitative susceptibility and the 10X factor for the inhalation study data gap.

LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure.

PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). BMD = benchmark dose. SD = standard deviation. BMD<sub>1SD</sub> = dose level where effect is 1 SD from control value. BMDL<sub>1SD</sub> = lower 95% confidence limit of the BMD value. BMDL<sub>10</sub> = dose which has a 10% toxicity change from the controls.

### 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 and those being established in response to the Agency issuing section 18 emergency exemptions, 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. Such effects were identified for bifenthrin. 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 established food uses as well as the petitioned for tolerances and the section 18 time-limited tolerances. Anticipated residues (ARs) were developed based on the following: USDA's Pesticide Data Program (PDP) monitoring data from 1998–2010 for bell pepper, blueberry, broccoli, cabbage, cauliflower, cilantro, cranberry, cucumber, egg, eggplant, grape, grapefruit, orange, orange juice, lettuce, pear, cantaloupe, winter squash, spinach—canned, succulent bean, strawberry, sweet corn, sweet peas,

tomato, watermelon and milk; the Food and Drug Administration (FDA) 2002 data for blackberry and raspberry; and field trial data for bifenthrin. ARs were further refined using percent crop treated (PCT) data and processing factors, where appropriate.

Additionally, the uses proposed under the section 18 emergency exemption program have use patterns that are similar to the registered use on pear. Therefore, the Agency relied on PDP data for pears, including for baby food and canned products, when assessing anticipated residues on peach, nectarine, and apple. EPA believes the use of PDP data for pears is appropriate, as bifenthrin residues are found mainly on the fruit surface and residues on peach, nectarine, and apple are expected to be similar to those found on pear.

ii. *Chronic exposure.* Based on the data summarized in Unit III.A., there is no increase in hazard from repeated exposures to bifenthrin; the acute dietary exposure assessment is protective for chronic dietary exposures because acute exposure levels are higher than chronic exposure levels.

Accordingly, a dietary exposure assessment for the purpose of assessing chronic dietary risk was not conducted.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., the Agency has determined that quantification of risk using a non-linear approach (i.e., aPAD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to bifenthrin. Additionally, since the cancer dietary assessment assumed average residue levels and the acute assessment used high-end residue levels, the acute dietary assessment will be protective of any cancer effects resulting from consumption of bifenthrin residues in foods.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated

residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

Alfalfa, 1%; almond, 25%; artichoke, 30%; beans, green, 50%; broccoli, 6%; cabbage, 30%; caneberries, 45%; canola/rapeseed, 3%; cantaloupe, 60%; carrots 10%; cauliflower, 10%; celery, 1%; corn, 5%; cotton, 10%; cucumbers, 15%; dry beans and peas, 1%; grape, table, 1%; grape, wine, 5%; honeydew, 75%; hazelnut (filberts), 5%; lettuce, 15%; onion, 1%; lima bean, 35%; peanut, 5%; pea, green, 25%; pear, 4%; pecan, 5%; pepper, 20%; pistachio, 40%; potato, 5%; pumpkin, 40%; sorghum, 1%; soybean, 5%; squash, 20%; strawberry, 55%; sweet corn, 50%; tomato, 20%; walnut, 25%; watermelon, 15%; wheat, spring, 1%; and wheat, winter, 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 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency estimated the PCT for the new uses associated with the time-limited tolerances as follows:

Apple, 10%; nectarine, 3%; and peach, 7%.

Bifenthrin is being considered for use on apple, nectarine, and peach in Delaware, Maryland, New Jersey, North Carolina, Pennsylvania, Virginia, and West Virginia to control the brown marmorated stink bug under FIFRA section 18, which allows for the emergency use of a pesticide on a site for which it is not registered.

The Agency conservatively estimated that 100 percent of the crops in these states will be treated with bifenthrin and calculated the national PCT given the share of utilized production or grown acreage from the seven states likely to seek the use of bifenthrin.

EPA used data from 2010 USDA/NASS for apples and peaches. Data on the most recent survey years, 2007–2009, were used to derive the needed PCT estimates. The sum of the utilized production in these states was divided by the total domestic utilized production and multiplied by 100 to determine the PCT for each of the crops for each of the named years.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations, including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's

exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which bifenthrin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for 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), Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of bifenthrin for acute exposures are estimated to be 0.0140 parts per billion (ppb) for surface water and 0.0030 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 0.0140 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Bifenthrin is currently registered for several uses that could result in residential exposures: In indoor residential/household premises as a crack and crevice spray, paint additive and as a dust, in or on automobiles/recreational vehicles, and for termite treatments. Residential exposure is also anticipated from a pending registration for bed bug treatment use, including surface-directed application to indoor surfaces. Outdoor residential uses of bifenthrin include broadcast and spot treatments to residential lawns and turf; golf course turf and outdoor premises by means of liquid spray and granular products; and ornamental uses (turf, shrubs, vines, trees, ground cover). EPA assessed

residential handler and post-application exposures for the existing and proposed bed bug uses of bifenthrin.

The Agency combines risk values resulting from separate routes of exposure when it is likely they can occur simultaneously based on the use pattern and the behavior associated with the exposed population, and if the hazard associated with the points of departure is similar across routes. A common toxicological endpoint, neurotoxicity, exists for dermal, incidental oral, and inhalation routes of exposure to bifenthrin. Therefore, these were combined for all residential exposure scenarios assessed.

Of the proposed and established uses with potential residential handler and post-application exposure, the following high-end risk estimates were selected for use in the bifenthrin short-term aggregate assessment: Combined dermal and inhalation exposures to adults from the outdoor ornamental use and combined dermal and incidental oral exposures to children from contact with treated turf.

Residential handler and post-application exposure scenarios are generally not combined. Although the potential exists for the same individual (i.e., adult) to apply a pesticide around the home and be exposed by re-entering a treated area in the same day, this is an unlikely exposure scenario. Combining these exposure scenarios would also be inappropriate because of the conservative nature of each individual assessment.

EPA did not assess intermediate-term and chronic residential exposures because bifenthrin is acutely toxic and does not increase in potency with repeated dosing. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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

The Agency is required to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. The Agency has determined that the pyrethroids and pyrethrins, including bifenthrin, share a common mechanism of toxicity. The members of this group share the ability to interact

with voltage-gated sodium channels, ultimately leading to neurotoxicity. The cumulative risk assessment for the pyrethroids/pyrethrins was published in the **Federal Register** on November 9, 2011 (76 FR 69726) (FRL-8888-9), and is available at <http://www.regulations.gov> in the public docket, EPA-HQ-OPP-2011-0746. Further information about the determination that pyrethroids and pyrethrins share a common mechanism of toxicity may be found in document ID number: EPA-HQ-OPP-2008-0489-0006.

The Agency has conducted a quantitative analysis of the proposed bifenthrin bed bug use and has determined that it will not contribute significantly or change the overall findings presented in the pyrethroid cumulative risk assessment. This analysis is summarized in the document: "Bifenthrin: Human Health Risk Assessment to Support Section 3 New Uses for a Bed Bug Treatment, Grass Grown for Seed, Tolerances for Imported Tea, and a Section 18 Emergency Exemption Use on Apple, Nectarine, and Peach" at pages 78-81 in docket ID number EPA-HQ-OPP-2009-1008. Further, the proposed food uses of bifenthrin will not contribute significantly or change the overall findings in the pyrethroid cumulative risk assessment, as the dietary risks are a minor component of total pyrethroid cumulative risk. For information regarding EPA's efforts to evaluate the risk of exposure to pyrethroids, refer to <http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html>.

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

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10x) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines based on reliable data, that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the 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 are available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The bifenthrin toxicity database includes developmental toxicity studies in rats and rabbits, a 2-generation reproduction study in rats, and a

developmental neurotoxicity (DNT) study in rats. Bifenthrin is neither a developmental nor a reproductive toxicant. In the developmental toxicity studies in rat and rabbit, no developmental effects of biological significance were noted in either species in the presence of maternal toxicity. In a 2-generation reproduction study in the rat, tremors were noted only in females of both generations with one parental generation rat observed to have clonic convulsions.

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

3. **Conclusion.** Given different levels of uncertainty for various risk assessment scenarios, EPA is applying different FQPA safety factors for the protection of fetuses, infants, and children depending on the route of exposure and the population exposed. For non-inhalation exposure scenarios for adults (including women of child-bearing age) and children greater than 6 years of age, EPA is reducing the FQPA safety factor to 1X. For non-inhalation exposure scenarios for infants and children less than six years of age, EPA is reducing the FQPA safety factor to 3X. Finally, for inhalation exposure scenarios for all population groups, EPA is also retaining a 10X FQPA safety factor. Because the 3X factor for infants and children less than six years of age and the 10X factor for inhalation exposure scenarios are in response to different uncertainties, these safety factors have been combined for inhalation exposure scenarios for infants and children less than six years of age resulting in a FQPA safety factor

of 30X. That decision on the various levels of the FQPA safety factor is based on the following considerations:

i. The toxicity database for bifenthrin is not complete. EPA lacks additional data on immunotoxicity, inhalation toxicity, and adult-juvenile sensitivity. Recent changes to 40 CFR part 158 imposed new data requirements for immunotoxicity testing (OCSP Guideline 870.7800) for pesticide registration. The toxicology database for bifenthrin does not show any evidence of treatment-related effects on the immune system, and the overall weight-of-evidence suggests that this chemical does not directly target the immune system. Therefore, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently in use for overall risk assessment, and additional safety factors are not needed to account for a lack of this study. EPA is requiring an inhalation toxicity study for bifenthrin because inhalation data for other pyrethroids show the potential for the inhalation route to be more potent than the oral route. Currently, the POD for inhalation risk assessment scenarios is based on an oral toxicity study. Reliance on an oral study raises uncertainty as to whether the standard safety factors are protective of infants and children. Finally, in light of the literature studies indicating a possibility of increased sensitivity to bifenthrin in juvenile rats at high doses, EPA has also requested proposals for study protocols which could identify and quantify bifenthrin's potential juvenile sensitivity. For the reasons discussed in Unit III.D.3.ii., the uncertainty regarding the protectiveness of the intraspecies uncertainty factor raised by the literature studies and the absence of the requested data warrant application of an additional 3X for risk assessments for infants and children under six years of age.

ii. There is no evidence that bifenthrin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. This is consistent with the results of the guideline pre- and post-natal testing for other pyrethroid pesticides. There are, however, high dose LD<sub>50</sub> studies (studies assessing what dose results in lethality to 50 percent of the tested population) in the scientific literature indicating that pyrethroids can result in increased quantitative sensitivity in the young. Examination of pharmacokinetic and pharmacodynamic data indicates that the sensitivity observed at high doses is related to pyrethroid age-

dependent pharmacokinetics—the activity of enzymes associated with the metabolism of pyrethroids. Predictive pharmacokinetic models indicate that the differential adult-juvenile pharmacokinetics will result in otherwise equivalent administered doses for adults and juveniles producing a 3X greater dose at the target organ in juveniles compared to adults. No evidence of increased quantitative or qualitative susceptibility was seen in the pyrethroid scientific literature related to pharmacodynamics (the effect of pyrethroids at the target tissue) both with regard to inter-species differences between rats and humans and to differences between juveniles and adults. Specifically, there are *in vitro* pharmacodynamic data and *in vivo* data indicating similar responses between adult and juvenile rats at low doses and data indicating that the rat is a conservative model compared to the human based on species-specific pharmacodynamics of homologous sodium channel isoforms in rats and humans.

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

iii. There are no residual uncertainties identified in the bifenthrin databases

with regard to dietary (food and drinking water), and residential exposures. Although the acute dietary exposure estimates are refined, as described in Unit III.C.1.i., the exposure estimates will not underestimate risk for the established and proposed uses of bifenthrin since the residue levels used are based on either monitoring data reflecting actual residues found in the food supply, or on high-end residues from field trials which reflect the use patterns which would result in highest residues in foods. Furthermore, processing factors used were either those measured in processing studies, or default high-end factors representing the maximum concentration of residue into a processed commodity. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to bifenthrin in drinking water. Further, postapplication exposure of children and incidental oral exposure of toddlers are based on conservative, health-protective assumptions that also ensure exposures are not underestimated. These assessments will not underestimate the exposure and risks posed by bifenthrin.

Further information about the reevaluation of the FQPA safety factor for pyrethroids may be found in document ID number: EPA-HQ-OPP-2011-0746-0011.

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

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

1. *Acute risk.* Using the assumptions discussed in this unit for acute exposure, at the 99.9th percentile of exposure the acute dietary exposure from food and water to bifenthrin will occupy 5% of the aPAD for the general U.S. population and 29% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

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

aggregate assessment is protective of potential chronic aggregate exposures.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Bifenthrin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to bifenthrin.

For children 1–2 years old, the most highly exposed children's subgroup, using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposures result in an aggregate MOE of 330. Because EPA's level of concern for bifenthrin is a MOE of 300 or below, this MOE is not of concern.

For adults, although the short-term dermal and inhalation risks were estimated using the same oral POD, these exposure estimates could not be directly combined for the adult short-term exposure assessment because the LOCs for dermal and inhalation routes of exposure are not the same (an MOE of < 100 defines the LOC for dermal exposure while inhalation risk is defined by an MOE of < 1,000). Accordingly an aggregate index (ARI) was required to estimate aggregate risk for adults. EPA identifies an ARI at or below one as a risk estimate of concern. The short-term aggregate ARI for adults is 2.0. An ARI greater than 1 indicates risks that are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term aggregate risk assessment was not conducted because bifenthrin is acutely toxic and does not increase in potency with repeated dosing. Because the neurotoxicity POD used for acute risk assessment is lower (more protective) than PODs for longer durations of exposure and acute and short-term exposure levels are higher than longer term exposure levels, the acute and short-term aggregate assessments are protective for intermediate-term aggregate risks anticipated from bifenthrin exposure.

5. *Aggregate cancer risk for U.S. population.* For the reasons discussed in Unit III.A. (cancer effects are non-linear and appear at higher doses than acute effects) and Unit III.E.2. (chronic

exposures are lower than acute exposures), the acute aggregate assessment is protective of potential cancer risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes with 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*

An adequate method, utilizing gas chromatography with electron capture detection (GC/ECD), is available to enforce the proposed tolerances for plant commodities.

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

### *B. International Residue Limits*

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

The Codex has not established an MRL for bifenthrin. However, Codex has proposed a 30 ppm MRL for green and black tea (fermented and dried). The United States has recommended a tolerance on tea, dried at 30 ppm in order to harmonize with the proposed Codex MRL.

### *C. Response to Comments*

EPA received one comment to the notice of filing that stated, in part, that no residue should be allowed for bifenthrin. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing

legal framework provided by section 408 of the FFDCa states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

*D. Revisions to Petitioned-for Tolerances*

Based on the data supporting the petitions, EPA revised the proposed tolerance on grass, forage from 2.5 ppm to 4.0 ppm; and grass, hay from 4.5 ppm to 15 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures. Additionally, EPA revised the proposed tolerance on tea from 25 ppm to 30 ppm, in order to harmonize with the proposed Codex MRL associated with the commodity. EPA also revised the proposed commodity definition for tea to tea, dried in order to reflect the correct commodity nomenclature.

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

**V. Conclusion**

Therefore, tolerances are established for residues of bifenthrin, (2-methyl [1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate, in or on grass, forage at 4.0 ppm; grass, hay at 15 ppm; and tea, dried at 30 ppm. This regulation additionally establishes time-limited tolerances for residues of bifenthrin in or on apple, nectarine, and peach at 0.5 ppm. Finally, this regulation removes time-limited tolerances 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 FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCa section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology

Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

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

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

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

Dated: September 10, 2012.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR part 180 is amended as follows:

**PART 180—[AMENDED]**

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

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

- 2. In § 180.442:
  - a. Revise paragraph (a)(1) introductory text.
  - b. Add alphabetically the commodity to the table in paragraph (a)(1).
  - c. Revise the footnote to the table in paragraph (a)(1).
  - d. Revise paragraph (b).
  - e. Revise paragraph (c).

The revisions and addition read as follows:

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

(a) *General.* (1) Tolerances are established for residues of the insecticide bifenthrin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only bifenthrin, (2-methyl [1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate.

Commodity	Parts per million
* * * * *	*
Tea, dried <sup>1</sup> .....	30
* * * * *	*

<sup>1</sup> There are no U.S. registrations.

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the insecticide bifenthrin, including its metabolites and degradates, in connection with use of the pesticide under a Section 18 emergency exemption granted by EPA. Compliance with the tolerance levels specified below is to be determined by measuring only bifenthrin, (2-methyl [1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate. These tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Apple .....	0.5	12/31/2015
Nectarine .....	0.5	12/31/2015
Peach .....	0.5	12/31/2015

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the insecticide bifenthrin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only bifenthrin, (2-methyl [1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate.

Commodity	Parts per million
Grass, forage .....	4.0
Grass, hay .....	15

\* \* \* \* \*

[FR Doc. 2012-22772 Filed 9-13-12; 8:45 am]

BILLING CODE 6560-50-P

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 665**

[Docket No. 120628195-2414-02]

RIN 0648-XC089

**Main Hawaiian Islands Deep 7 Bottomfish Annual Catch Limits and Accountability Measures for 2012-13**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final specifications.

**SUMMARY:** In this rule, NMFS specifies a quota of 325,000 lb of Deep 7 bottomfish in the main Hawaiian Islands for the 2012-13 fishing year, based on an annual catch limit of 346,000 lb. The action supports the long-term sustainability of Hawaii bottomfish.

**DATES:** The final specifications are effective October 15, 2012 through August 31, 2013, unless NMFS publishes a document in the **Federal Register** superseding these specifications.

**ADDRESSES:** Copies of the Fishery Ecosystem Plan for the Hawaiian Archipelago are available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808-522-8220, fax 808-522-8226, or [www.wpcouncil.org](http://www.wpcouncil.org).

**FOR FURTHER INFORMATION CONTACT:** Jarad Makaiau, NMFS PIR Sustainable Fisheries, 808-944-2108.

**SUPPLEMENTARY INFORMATION:** On August 2, 2012, NMFS published proposed specifications that are finalized here, and a request for public comments (77 FR 46014). Additional background information on this action is found in the preamble to the proposed specifications, and is not repeated here.

Through this action, NMFS is specifying a quota (annual catch target, ACT) of 325,000 lb of Deep 7 bottomfish in the main Hawaiian Islands (MHI) for the 2012-13 fishing year, based on an annual catch limit (ACL) of 346,000 lb. The MHI Management Subarea is the portion of U.S. Exclusive Economic Zone around the Hawaiian Archipelago lying to the east of 161° 20' W. longitude. The Deep 7 bottomfish are onaga (*Etelis coruscans*), ehu (*E. carbunculus*), gindai (*Pristipomoides zonatus*), kalekale (*P. sieboldii*), opakapaka (*P. filamentosus*), lehi (*Aphareus rutilans*), and hapuupuu (*Epinephelus quernus*). The Council recommended the quota and ACL based on the best available scientific, commercial, and other information, taking into account the associated risk of overfishing.

The MHI bottomfish fishing year starts September 1, 2012. NMFS will monitor the fishery, and if the is quota is projected to be reached before August 31, 2013, NMFS will close the non-commercial and commercial fisheries for Deep 7 bottomfish in Federal waters through August 31, 2013. During a fishery closure for Deep 7 bottomfish, no person may fish for, possess, or sell any of these fish in the MHI, except as otherwise authorized by law (specifically, vessels with valid Pacific

Remote Island Areas bottomfish fishing permits are not affected by the closure). There is no prohibition on fishing for or selling other non-Deep 7 bottomfish species throughout the year. All other management measures continue to apply in the MHI bottomfish fishery.

**Comments and Responses**

The comment period for the proposed specifications ended on August 17, 2012. NMFS received comments and responds as follows:

*Comment 1:* The annual catch limit is a management tool that will ensure fish stocks for future generations to come.

*Response:* NMFS agrees. Federal law requires NMFS and the Council to manage fisheries using annual catch limits. NMFS and the Council developed the annual catch limit using the best available scientific and commercial information and in consideration of scientific uncertainty and social and economic factors. The use of an annual catch limit, annual catch target and accountability measure will help prevent overfishing and ensure sustainable, long-term catches for fishermen.

*Comment 2:* The combination of measures to prevent overfishing by the Federal government (through ACL and AM), and by the State of Hawaii (through spatial restrictions, or bottomfish restricted fishing areas) are duplicative, disadvantaging certain fishing communities, and NMFS should remove the bottomfish restricted fishing areas, or at least those in Federal waters.

*Response:* While the State and Federal bottomfish regulations may appear to be duplicative, they are not. In 1998, the State of Hawaii established by administrative rule the bottomfish restricted fishing areas. At that time, in the absence of Federal regulations these areas were intended specifically to prevent overfishing. Some of the restricted areas were located in Federal waters. The Council and NMFS recognized that the administration and enforcement of these areas were and continue to be, the responsibility of the State, and any change to the management of the bottomfish restricted fishing areas is the purview of the State.

The Council subsequently (in 2008) developed, and NMFS implemented, the first Hawaii bottomfish quota system. The Federal quota measures complement, but do not duplicate, State restricted area measures. The combined State and Federal bottomfish management programs include a mix of minimum fish sizes, non-commercial bag limits, restricted fishing areas, catch limits, gear restrictions, permits and