appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rules do not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will they impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by 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 these actions 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. These actions are not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of these actions must be filed in the United States Court of Appeals for the appropriate circuit by February 21, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of these actions for the 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. These actions 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.

Dated: December 6, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart Z—Mississippi

■ 2. Section 52.1270(e) is amended by adding a new entry ''Good Neighbor Provisions (Section 110(a)(2)(D)(i)(I)) for the 2010 1-hour NO_2 NAAQS'' at the end of the table to read as follows:

§ 52.1270 Identification of plan.

* * * * *

(e) * * *

EPA APPROVED MISSISSIPPI NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
*	*	*	*	*
Good Neighbor Provisions (Section 110(a)(2)(D)(i)(I) for the 2010 1-hour NO_2 NAAQS.	Mississippi	5/23/2016	12/22/16, [Insert **Federal Register** citation]	

[FR Doc. 2016–30641 Filed 12–21–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0236; FRL–9954–47]

Bifenthrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of bifenthrin in or on avocado and pomegranate. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on avocado and pomegranate.

This regulation establishes a maximum permissible level for residues of bifenthrin in or on these commodities. The time-limited tolerances expire on December 31, 2019.

DATES: This regulation is effective December 22, 2016. Objections and requests for hearings must be received on or before February 21, 2017, 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–2016–0236, 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), West William Jefferson Clinton 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: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the 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 section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 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–2016–0236 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 February 21, 2017. 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–2016–0236, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for residues of bifenthrin, (2-methyl[1,1′-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane-carboxylate), in or on avocado at 0.50 parts per million (ppm) and pomegranate at 0.50 ppm. These time-limited tolerances expire on December 31, 2019.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.,* without having received any petition from an outside party.

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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Bifenthrin on Avocado and Pomegranate and FFDCA Tolerances

The California Department of Pesticide Regulations (CDPR) requested an emergency exemption for the use of bifenthrin on avocados to control the polyphagous shot hole borer (PSHB), *Euwallacea sp.* near *fornicatus.* PSHB is a non-native ambrosia beetle that is only known to exist in Israel and now California, where it is a pest for avocados and numerous ornamental species. According to CDPR, substantial economic damage is occurring and 50% of baseline net operating revenue has been documented due to the inadequate efficacy and short residual activity of registered alternatives.

CDPR also requested an emergency exemption for the use of bifenthrin on pomegranate to control leaffooted plant bug (LFPB), *Leptoglossus clypealis, L. occidentalis, and L. zonatus.* LFPBs are highly damaging pests for pomegranates. According to CDPR, substantial economic damage is occurring and 32% gross revenue loss is expected due to registered alternatives short residual activity and ineffective control of adult LFPB.

After having reviewed the submission, EPA determined that an emergency condition exists in California, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of bifenthrin on avocado for control of polyphagous shot hole borer in California. Additionally, EPA has authorized crisis and specific exemptions under FIFRA section 18 for the use of bifenthrin on pomegranate to control leaffooted plant bug in California.

As part of its evaluation of the emergency exemption applications, EPA assessed the potential risks presented by residues of bifenthrin in or on avocados and pomegranates. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) 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 FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2019, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on avocados and pomegranate 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 about whether bifenthrin meets FIFRA's registration requirements for use on avocados and pomegranate or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of bifenthrin by a State for special local needs under FIFRA section 24(c), nor do these tolerances by themselves serve as the authority for persons in any State other than California to use this pesticide on the applicable 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**.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of, and to make a determination on, aggregate exposures expected as a result of these emergency exemption requests and the time-limited tolerances for residues of bifenthrin on avocado at 0.50 ppm and pomegranate at 0.50 ppm. EPA's assessment of exposures and risks associated with establishing time-limited tolerances follows.

A. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (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. 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 discussed in Table 1 of the final rule published in the **Federal Register** of September 14, 2012, 77 FR 56782 (FRL–9361–6).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bifenthrin, EPA considered exposure under the time-limited tolerances established by this action 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.* Acute effects were identified for bifenthrin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA and the Dietary Exposure Evaluation Model-Food Consumption Intake Database (DEEM–FCID, version 3.16). As to residue levels in food, EPA developed anticipated residues (ARs) based on the latest USDA Pesticide Data Program (PDP) monitoring data 1998–2010, Food and Drug Administration (FDA) data, and field trial data (FTD) for bifenthrin. The assessment also made use of percent crop treated (PCT) data where available.

ii. *Chronic exposure.* EPA determined that there is no increase in hazard from repeat exposures to bifenthrin. Therefore, 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 IV.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to bifenthrin. Cancer risk was assessed using the same exposure estimates as discussed in Unit IV.B.1.ii., *chronic exposure.*

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 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%; apple, 10%; 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%; nectarine, 3%; peanut, 5%; pea, green, 25%; peach, 7%; pear, 1%; 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 and averaging across all observations. 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 assumed 100% PCT for avocado and pomegranate uses.

The Agency believes that the three conditions discussed in Unit IV.B1.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. 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.

The previous dietary exposure assessment for use avocado relied on PCT estimates generated in 2011; however, recently updated bifenthrin PCT information (Screening Level Estimates of Agricultural Uses of Bifenthrin from 2005–2014; Updated Screening Level Usage Analysis (SLUA) report for Bifenthrin (03/24/2016)) have become available for consideration. When comparing the PCT estimates used previously with those that were updated in 2016, some individual PCT estimates increased, and some decreased. For most foods (*e.g.,* apples, green beans, grapes, peaches) which are typically risk drivers for the infants and children's populations who have highest estimated risks, the PCT data used in the previous assessment have not increased significantly or at all. Crops with significant increases (≤ 15% CT) are generally not those which are typically risk drivers (*e.g.,* artichokes, cabbage, canola). A significant children's food for which PCT increased significantly (25% to 50%CT) is green peas; however, since bifenthrin residues in peas are non-detectable in PDP monitoring data, a significant increase in estimated risks is not expected. Similarly, for other crops with smaller increases in PCT (almonds, sweet corn, peanuts, pecans, pistachios, and walnuts) detectable residues are not found; therefore, significant increases in dietary risk are not expected. While there are increases in PCT for some crops which are expected to lead to increased risk estimates (cucurbits, Cole crops, tomatoes, and some berries), the increased risk is expected to be small. Considering all of these factors, the updated PCT estimates are not expected to affect the results of the 2011 bifenthrin acute dietary risk assessment enough to warrant revising that assessment for this time limited tolerance decision. Even with the emergency use of bifenthrin on pomegranates, and the new PCT estimates, EPA remains confident that bifenthrin exposures are below the aPADs for all population subgroups.

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). Residential exposure is not anticipated from the use of bifenthrin on avocados and pomegranates because the emergency uses are restricted for use only by certified applicators and applicators under their direct supervision.

However, bifenthrin is currently registered for the following uses that could result in residential exposures: in indoor residential/household premises in the form of crack and crevice sprays, surface-directed application to indoor surfaces (bed bug treatment), as a paint additive, dust, automobiles/recreational vehicles and termite treatments. Outdoor residential uses of bifenthrin include broadcast and spot treatments including the following: Residential lawns and turf; golf course turf and outdoor premises (fencerows/hedgerows, paths/patios) by means of liquid spray and granular products; and ornamental (turf, shrubs, vines, trees, ground cover). EPA assessed residential exposure using the following assumptions: 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 on Nov. 9, 2011, 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: EPA–HQ–OPP–2008–0489–0006.

The Agency has conducted a quantitative analysis of the increased risk potential resulting from the section 18 use of bifenthrin on avocados and pomegranates; this analysis is summarized in the documents: ''Human Health Risk Assessment to Support Section 18 Specific Emergency Exemption Use on Avocado'' and ''Bifenthrin. Section 18 Request for Use on Pomegranate in California'' in docket ID number EPA–HQ–OPP–2016–0236. Since dietary exposures are a minor component of the overall pyrethroid cumulative risk, the uses on avocados and pomegranates will not contribute significantly or change the overall findings presented in the pyrethroid cumulative risk assessment. For information regarding EPA's efforts to evaluate the risk of exposure to pyrethroids, refer to *https://www.epa.gov/ingredients-used-pesticide-products/pyrethrins-and-pyrethroids#reg review.*

C. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The 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 Lethal Dose $(LD)_{50}$ 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.* The Agency is reducing the FQPA SF to 1X for adults, including women of child-bearing age, and children greater than 6 years of age, resulting in a total uncertainty factor of 100 (10x interspecies, 10x intraspecies, 1x FQPA). However, the Agency is retaining a 3X FQPA SF for children from birth to 6 years of age resulting in a total uncertainty factor of 300 (10x

interspecies, 10x intraspecies, 3x FQPA).

EPA has determined that reliable data show that the safety of infants and children less than or equal to 6 years old would be adequately protected if the FQPA SF were retained to 3X. That decision is based on the following findings:

i. The toxicity database for bifenthrin is complete.

ii. Like other pyrethroids, bifenthrin causes clinical signs of neurotoxicity from interaction with sodium channels. These effects are adequately assessed by the available guideline and non-guideline studies. Bifenthrin is a Type I pyrethroid, and neurotoxic effects characteristic of Type I pyrethroids were observed in adults in most of the bifenthrin toxicity database. Specifically, muscle tremors and decreased motor activity were observed in adults in guideline studies throughout the bifenthrin toxicology database, and hind-limb flexion was observed in adults the dermal study. For these reasons, the tremors seen in juveniles in the 2-generation reproduction study are not considered age-dependent effects.

iii. There is no evidence that bifenthrin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. This is consistent with the results of the guideline pre- and post-natal testing for other pyrethroid pesticides. There are, however, high dose LD_{50} 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 any additional data indicating a lack of elevated sensitivity to juveniles relative to adults, 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 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.

iv. There are no residual uncertainties identified in the exposure databases with regard to dietary (food and drinking water), and residential exposures. Although the acute dietary exposure estimates are refined, 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. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by bifenthrin.

D. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to bifenthrin will occupy 7% of the aPAD for the general U.S. population and 54% of the aPAD for infants <1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Based on the data summarized in Unit IV.B.ii., 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.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 250 for adults and 340 for children 1 < 2 years old, the most highly exposed population. Because EPA's level of concern (LOC) for bifenthrin is a MOE of 100 or less for adults and 300

for children 1<2, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, bifenthrin is not expected to pose an intermediate-term risk. An intermediate-term and/or chronic aggregate risk assessment was not conducted because bifenthrin is acutely toxic and 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.

5. *Aggregate cancer risk for U.S. population.* The acute aggregate assessment is protective of potential chronic aggregate exposures. For these same reasons, the acute aggregate assessment is also protective of potential cancer risk.

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

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (gas chromatography/electron capture detection) is available to enforce the tolerance expression.

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

B. International Residue Limits

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

The Codex has not established a MRL for bifenthrin in or on avocado and pomegranate.

VI. Conclusion

Therefore, time-limited 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-dimethylcyclopropane-carboxylate), in or on avocado at 0.50 ppm and pomegranate at 0.50 ppm. These tolerances expire on December 31, 2019.

VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA sections 408(e) and 408(l)(6). 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: November 10, 2016.

Michael Goodis,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. In § 180.442, revise paragraph (b) to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for

residues of the bifenthrin, (2-methyl[1,1′-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane-carboxylate) in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Apple	0.5	12/31/2018
Avocado	0.50	12/31/2019
Nectarine	0.5	12/31/2018
Peach	0.5	12/31/2018
Pomegranate	0.50	12/31/2019

* * * * *

[FR Doc. 2016–29882 Filed 12–21–16; 8:45 am]

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FEDERAL MARITIME COMMISSION

46 CFR Part 502

[Docket No. 16–08]

RIN 3072–AC64

Rules of Practice and Procedure; Presentation of Evidence in Commission Proceedings

AGENCY: Federal Maritime Commission.

ACTION: Final rule

SUMMARY: The Federal Maritime Commission is reorganizing several subparts of its Rules of Practice and Procedure and revising its rules regarding presentation of evidence in Commission proceedings.

DATES: Effective January 27, 2016.

FOR FURTHER INFORMATION CONTACT: Rachel E. Dickon, Assistant Secretary, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573–0001. *Phone:* (202) 523–5725. *Email: secretary@fmc.gov.*

SUPPLEMENTARY INFORMATION: The Commission is updating or reorganizing several subparts of 46 CFR part 502, its Rules of Practice and Procedure, and substantively revising the subpart regarding how hearings are conducted to improve guidance concerning the presentation of evidence in Commission proceedings. Certain current rules are also removed to clarify current practice and eliminate duplication.

On May 3, 2016, the Commission issued a Notice of Proposed Rulemaking (NPRM) seeking public comment on the proposed amendments. 81 FR 26517. The Commission received one comment in response to the NPRM from the American Association of Port Authorities (AAPA) that addressed proposed § 502.204, revising and renumbering § 502.156. Current § 502.156 states ''[u]nless inconsistent with the requirements of the Administrative Procedure Act and these Rules, the Federal Rules of Evidence . . . will also be applicable.'' As explained in the NPRM, the proposed revision is intended to simplify the language in the rule by restating the liberal Administrative Procedure Act (APA) standard for admissibility and also to provide that the presiding officer may continue to look to the Federal Rules of Evidence (FRE) for guidance.

The Commission adopted the original language in § 502.156 in 1976, shortly after the FRE went into effect. 41 FR 20585, 20588 (May 19, 1976). In the 1975 notice proposing the language the Commission asserted that, as a general matter, the FRE did not appear to be inconsistent with the APA and that the FRE could be of great use to the Commission's administrative law judges (ALJs) in disposing of evidentiary issues that arise in Commission proceedings, so long as they were consistent with the requirements of the APA. 40 FR 43295, 43927 (Sep. 24, 1975). Since promulgation of the section, however, the Commission ''has recognized the liberal standards of admissibility of evidence in administrative proceedings and has repeatedly '. . . identified the need for considerable relaxation of the rules of evidence followed by the federal courts in proceedings before the Commission.' '' *EuroUSA Shipping, Inc., Tober Group, Inc.—Possible Violations,* 31 S.R.R. 540, 547 (FMC 2008) (hereinafter *Tober*) (quoting *Pacific Champion Express Co., Ltd.—Possible Violations,* 28 S.R.R. 1102, 1105–06 (ALJ 1999)). Given the divergence between the FRE and APA standards, the current section's attempt to apply both standards simultaneously creates a tension in the regulation and could be confusing to parties. Accordingly, the Commission is now explicitly providing that presiding officers may look to the FRE for guidance when determining the admissibility of evidence. The AAPA notes that current rule § 502.156, states that the FRE ''will be applicable'' to Commission proceedings ''unless inconsistent with'' the requirements of the APA whereas the proposed language provides that the presiding officer ''may look to the FRE for guidance.'' The AAPA inquires whether such a change is intended to loosen the admissibility standard in cases before the Commission, and if so, to what to degree. The new rule does not loosen the admissibility standards, but rather clarifies, based on Commission and judicial precedent, that the standard of admissibility is governed by the APA, not the FRE. While the presiding officer may consider the FRE for guidance, they are neither controlling nor binding. In response to the AAPA's expressed concern that the revised language suggests a change in the presiding officer's discretion, we clarify the final rule by replacing the language ''look to the FRE for guidance'' with the language ''consider the FRE for guidance'' as it better reflects the discretion of the presiding officer.

The Commission recently addressed the utility of applying the FRE in proceedings before it in *Tober.* Pointing to its own precedent, the Commission noted that it has long recognized the liberal standards of admissibility of evidence in administrative proceedings and the need for considerable relaxation of the rules of evidence followed by the federal courts in proceedings before the Commission. Applying those standards to the ALJ's exclusion of certain exhibits on the basis of the FRE, the Commission held that challenged exhibits were admissible under the APA standard and that ''to the extent that the Commission's rules and the APA diverge from the FRE, the FRE are not controlling and the Commission is not bound by their requirements.'' *Id.,* 549.

The AAPA also states that the proposed rule could impact motions for summary judgment. It noted that in federal court, a party opposing a motion on the grounds that there are material facts in genuine dispute must show that there is admissible evidence on its side of the asserted dispute. The AAPA appears to be concerned that a loosening of the standard may limit the utility of summary judgment motions. The Commission addressed the admissibility of evidence in the context of motions for summary judgment in *Tober.* Citing the Supreme Court's decision in *Celotex Corp.* v. *Catrett,* 477 U.S. 317, 324 (1986), the Commission stated: ''While the nonmoving party is to show facts that present a genuine issue worthy of trial, *the nonmoving party at the summary judgment stage is not required to produce evidence in a form that would be admissible at trial.*'' *Id.,* 31 S.R.R. at 549 (emphasis added). Thus, the Commission made clear that at the summary judgment stage, the nonmoving party only needs to show facts that present a genuine issue worthy of trial. *Id.* This standard is applied to ensure that doubts are resolved in favor of the nonmoving party. As the Commission noted, it has denied summary judgment even when the nonmovant has not submitted any