

paragraph (d)(4) of this section to be cut in one harvest operation where the responsible official determines that larger harvest openings are necessary to help achieve desired ecological conditions in the plan area. If so, standards for exceptions shall include the particular conditions under which the larger size is permitted and must set a maximum size permitted under those conditions.

(ii) Plan components may allow for size limits exceeding those established in paragraphs (d)(4) introductory text and (d)(4)(i) of this section on an individual timber sale basis after 60 days public notice and review by the regional forester.

(iii) The plan maximum size for openings to be cut in one harvest operation shall not apply to the size of openings harvested as a result of natural catastrophic conditions such as fire, insect and disease attack, or windstorm (16 U.S.C. 1604(g)(3)(F)(iv)).

\* \* \* \* \*

Dated: November 23, 2021.

**Meryl Harrell,**

*Deputy Under Secretary, Natural Resources & Environment.*

[FR Doc. 2021-25947 Filed 11-30-21; 8:45 am]

BILLING CODE 3411-15-P

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## LIBRARY OF CONGRESS

### Copyright Royalty Board

#### 37 CFR Part 380

[Docket No. 19-CRB-0005-WR (2021-2025)  
COLA (2022)]

#### Cost of Living Adjustment to Royalty Rates for Webcaster Statutory License

**AGENCY:** Copyright Royalty Board (CRB), Library of Congress.

**ACTION:** Final rule; cost of living adjustment.

**SUMMARY:** The Copyright Royalty Judges announce a cost of living adjustment (COLA) in the royalty rates that commercial and noncommercial noninteractive webcasters pay for eligible transmissions pursuant to the statutory licenses for the public performance of and for the making of ephemeral reproductions of sound recordings.

**DATES:**

*Effective date:* January 1, 2022.

*Applicability dates:* These rates are applicable to the period January 1, 2022, through December 31, 2022.

**FOR FURTHER INFORMATION CONTACT:**

Anita Blaine, (202) 707-7658, [crb@loc.gov](mailto:crb@loc.gov).

**SUPPLEMENTARY INFORMATION:** Sections 112(e) and 114(f) of the Copyright Act, title 17 of the United States Code, create statutory licenses for certain digital performances of sound recordings and the making of ephemeral reproductions to facilitate transmission of those sound recordings. On October 27, 2021, the Copyright Royalty Judges (Judges) adopted final regulations governing the rates and terms of copyright royalty payments under those licenses for the license period 2021-2025 for performances of sound recordings via eligible transmissions by commercial and noncommercial noninteractive webcasters. See 86 FR 59452.

Pursuant to those regulations, at least 25 days before January 1 of each year from 2022 to 2025, the Judges shall publish in the **Federal Register** notice of a COLA applicable to the royalty fees for performances of sound recordings via eligible transmissions by commercial and noncommercial noninteractive webcasters. 37 CFR 380.10.

The adjustment in the royalty fee shall be based on a calculation of the percentage increase in the CPIU from the CPIU published in November 2020 (260.229), according to the formula: For subscription performances,  $(1 + (Cy - 260.229)/260.229) \times \$0.0026$ ; for nonsubscription performances,  $(1 + (Cy - 260.229)/260.229) \times \$0.0021$ ; for performances by a noncommercial webcaster in excess of 159,140 ATH per month,  $(1 + (Cy - 260.229)/260.229) \times \$0.0021$ ; where Cy is the CPI-U published by the Secretary of Labor before December 1 of the preceding year. The adjusted rate shall be rounded to the nearest fourth decimal place. 37 CFR 380.10(c). The CPIU published by the Secretary of Labor from the most recent index published before December 1, 2021, is 276.589.<sup>1</sup> Applying the formula in 37 CFR 380.10(c) and rounding to the nearest fourth decimal place results in an increase in the rates for 2022.

The 2022 rate for eligible transmissions of sound recordings by commercial webcasters is \$0.0028 per subscription performance and \$0.0022 per nonsubscription performance.

Application of the increase to rates for noncommercial webcasters results in a 2022 rate of \$0.0022 per performance for all digital audio transmissions in excess of 159,140 ATH in a month on a channel or station.

As provided in 37 CFR 380.10(d), the royalty fee for making ephemeral

<sup>1</sup> This CPI-U was announced on November 10, 2021, by the Bureau of Labor Statistics in its *Consumer Price Index News Release—Consumer Price Index*, available at <https://www.bls.gov/news.release/cpi.htm> at Table 1.

recordings under section 112 of the Copyright Act to facilitate digital transmission of sound recordings under section 114 of the Copyright Act is included in the section 114 royalty fee and comprises 5% of the total fee.

#### List of Subjects in 37 CFR Part 380

Copyright; Sound recordings.

#### Final Regulations

In consideration of the foregoing, the Judges amend part 380 of title 37 of the Code of Federal Regulations as follows:

#### PART 380—RATES AND TERMS FOR TRANSMISSIONS BY ELIGIBLE NONSUBSCRIPTION SERVICES AND NEW SUBSCRIPTION SERVICES AND FOR THE MAKING OF EPHEMERAL REPRODUCTIONS TO FACILITATE THOSE TRANSMISSIONS

■ 1. The authority citation for part 380 continues to read as follows:

**Authority:** 17 U.S.C. 112(e), 114(f), 804(b)(3).

■ 2. Section 380.10 is amended by revising paragraph (a) to read as follows:

#### § 380.10 Royalty fees for the public performance of sound recordings and the making of ephemeral recordings.

(a) *Royalty fees.* For the year 2022, Licensees must pay royalty fees for all Eligible Transmissions of sound recordings at the following rates:

(1) *Commercial webcasters:* \$0.0028 per Performance for subscription services and \$0.0022 per Performance for nonsubscription services.

(2) *Noncommercial webcasters:* \$1,000 per year for each channel or station and \$0.0022 per Performance for all digital audio transmissions in excess of 159,140 ATH in a month on a channel or station.

\* \* \* \* \*

Dated: November 23, 2021.

**Suzanne M. Barnett,**

*Chief Copyright Royalty Judge.*

[FR Doc. 2021-26062 Filed 11-30-21; 8:45 am]

BILLING CODE 1410-72-P

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2016-0352 and EPA-HQ-OPP-2019-0560; FRL-8945-01-OCSP]

#### Bifenthrin; Pesticide Tolerances

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

**ACTION:** Final rule.

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**SUMMARY:** This regulation establishes tolerances for residues of bifenthrin in or on multiple commodities which are identified and discussed later in this document. The Interregional Project Number 4 (IR-4) and FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective December 1, 2021. Objections and requests for hearings must be received on or before January 31, 2022 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 dockets for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0352 and EPA-HQ-OPP-2019-0560, are 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Acting Director, 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](mailto: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 EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

###### *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 numbers EPA-HQ-OPP-2016-0352 and EPA-HQ-OPP-2019-0560 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 January 31, 2022. 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 numbers EPA-HQ-OPP-2016-0352 and EPA-HQ-OPP-2019-0560, 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 <https://www.epa.gov/dockets/where-send-comments-epa-dockets>. 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 October 18, 2016 (81 FR 71668) (FRL-9952-19), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8482) by IR-4, Rutgers, the State University of New Jersey, 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 apple, wet pomace at 1.3 parts per million (ppm); avocado at 0.50 ppm; berry, low growing, subgroup 13-07G at 3.0 ppm; *Brassica*, leafy greens, subgroup 4-16B at 15 ppm; caneberry subgroup 13-07A at 1.0 ppm; fruit, citrus, group 10-10 at 0.05 ppm; fruit, pome, group 11-10, except mayhaw, at 0.70 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.20 ppm; nut, tree, group 14-12 at 0.05 ppm; peach, subgroup 12-12B at 0.70 ppm; pepper/eggplant subgroup 8-10B at 0.50 ppm; pomegranate at 0.50 ppm; and tomato, subgroup 8-10A at 0.15 ppm. The October 18, 2016, **Federal Register** document and the Notice of Filing in docket number EPA-HQ-OPP-2016-0352 identified the requested tolerance for tomato subgroup 8-10A as 0.30 ppm. However, IR-4's submitted petition identified a tolerance of 0.15 ppm for tomato subgroup 8-10A. When there is a discrepancy between a tolerance in the submitted Notice of Filing and the submitted petition, EPA uses the tolerance in the petition as the petitioned-for tolerance, which is 0.15 ppm for tomato subgroup 8-10A.

Additionally, the petition requested, upon approval of the above tolerances, to remove the existing tolerances in 40 CFR 180.442(a) in or on *Brassica*, leafy greens, subgroup 5B at 3.5 ppm; caneberry, subgroup 13A at 1.0 ppm; eggplant 0.05 ppm; fruit, citrus, group 10 at 0.05 ppm; grape at 0.20 ppm; groundcherry at 0.5 ppm; nut, tree, group 14 at 0.05 ppm; okra at 0.50 ppm; pear at 0.5 ppm; pepino at 0.5 ppm; pepper, bell at 0.5 ppm; pepper, non-bell at 0.5 ppm; pistachio at 0.05 ppm; strawberry at 3.0 ppm; tomato at 0.15

ppm; and turnip, greens at 3.5 ppm. Finally, the petition requested upon approval of the above tolerances, to remove the existing time-limited tolerances in 40 CFR 180.442(b) in or on, apple at 0.5 ppm; nectarine at 0.5 ppm; and peach at 0.5 ppm. That document referenced a summary of the petition prepared by FMC Corporation and Makhteshim Agan of North America, Inc. (ADAMA), the registrants, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

In the **Federal Register** of February 11, 2020 (85 FR 7708) (FRL-10005-02), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F8704) by FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104. The petition requested that 40 CFR 180.442 be amended by establishing tolerances for residues of the bifenthrin, (2-methyl [1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate, in or on sunflower (crop subgroup 20B) at 0.01 ppm. That document referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions, EPA is establishing some tolerances that vary from what was requested. The reasons for these changes are explained in Unit IV.C.

### III. Aggregate Risk Assessment and Determination of Safety

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

aggregate exposure to the pesticide chemical residue. . . ."

Consistent with FFDCA section 408(b)(2)(D), and 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 exposure for bifenthrin including exposure resulting from the 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.

The predominant effects seen in most of the bifenthrin experimental toxicology studies were behavioral changes characteristic of Type I pyrethroids, such as muscle tremors, which are consistent with its mode-of-action (MOA) to activate sodium channels. Additional effects seen in one or more studies 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 and food consumption were also noted in repeat-dosing dietary studies.

In developmental toxicity studies involving rats and rabbits, maternal toxicity was observed (neurological effects) while no developmental effects of biological significance were observed. In the 2-generation reproduction dietary study in the rat, tremors were noted only in females of both generations, with one parental generation rat observed to have clonic convulsions, and no observed effects in the offspring. A developmental neurotoxicity study was also conducted. Clinical signs of neurotoxicity were observed in both the adults and offspring at the same dose levels; therefore, there is no indication of increased qualitative or quantitative susceptibility in the young.

Bifenthrin is classified as a Group C—"possible human carcinogen," based on an increased incidence of urinary bladder tumors in mice. However, EPA has determined that quantification of risk using a non-linear approach (*i.e.*,

reference dose (RfD)) will adequately account for all chronic toxicity, including potential carcinogenicity, that could result from exposure to bifenthrin for the following reasons. First, the bladder tumors may not be uncommon in mice and are not likely to be malignant. Second, these tumors were observed only in male mice at the highest dose. Third, no evidence of carcinogenicity was observed in bifenthrin carcinogenicity studies in rats. Finally, there is a low concern for mutagenicity based on the overall results of the available mutagenicity tests of bifenthrin.

A complete discussion of the toxicological profile for bifenthrin and the Agency's cancer conclusion as well as specific information on the studies received and the nature of the adverse effects caused by bifenthrin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in the documents titled "Bifenthrin: Revised Human Health Risk Assessment for the Requested Section 3 Registration of Bifenthrin on Pome Fruit Group 11-10 (except Mayhaw), Peach Subgroup 12-12B, Avocado, Pomegranate, *Brassica* Leafy Greens Subgroup 4-16B; and Crop Group Conversions/Expansions for Tomato Subgroup 8-10A, Pepper/Eggplant Subgroup 8-10B, Small Vine Climbing Fruit Subgroup 13-07F, Low Growing Berry Subgroup 13-07G, Citrus Fruit Group 10 to Citrus Fruit Group 10-10, Caneberry Subgroup 13A to Caneberry Subgroup 13-07A, and Tree Nut Group 14 to Tree Nut Group 14-12" (hereinafter "Bifenthrin Multiple Crop Human Health Risk Assessment") and "Bifenthrin. Human Health Risk Assessment for the Proposed New Use on Sunflower Crop Subgroup 20B" in docket ID number EPA-HQ-OPP-2016-0352 in [regulations.gov](http://www.regulations.gov).

#### B. 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for bifenthrin used for human risk assessment can be found in the Bifenthrin Multiple Crop Human Health Risk Assessment.

### C. Exposure Assessment

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

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for bifenthrin. In estimating acute dietary exposure, EPA used 2003–2008 food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWELA). As to residue levels in food, the acute assessment was refined using distributions and point estimates derived from pesticide data program (PDP) monitoring data, field trial data, percent crop treated (PCT) data, and empirical processing factors.

ii. *Chronic exposure.* A chronic dietary endpoint has not been selected for bifenthrin because repeated exposure does not result in a POD lower than that resulting from acute exposure; therefore, the acute dietary risk assessment is protective of chronic dietary risk. However, since there are residential uses of bifenthrin, a refined chronic dietary exposure assessment was conducted to calculate average (food and drinking water) exposure estimates representing background

dietary exposure to support the bifenthrin aggregate risk assessment. The assessment was refined using point estimates derived from PDP monitoring data, field trial data, PCT data, and empirical processing factors.

iii. *Cancer.* As discussed in Unit III.A., EPA has determined that the acute reference dose (RfD) will adequately account for all repeated exposure/chronic toxicity, including potential carcinogenicity, which could result from exposure to bifenthrin. A separate cancer exposure assessment was not conducted.

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, and 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 acute dietary assessment used the following maximum PCT estimates: Almonds: 40%, artichoke: 65%, green beans (fresh & succulent): 60%, blueberries (all bushberries): 35%, broccoli: 25%, Brussel sprouts: 5%, cabbage: 50%, caneberries: 55%, canola: 25%, cantaloupes: 55%, carrots: 5%, cauliflower: 2.5%, celery: 45%, citrus

(all others): 2.5%, corn: 10%, cotton: 20%, cucumbers: 35%, dry beans/peas: 5%, eggplant: 45%, grapefruit: 2.5%, grapes, juice: 10%, grapes, table: 2.5%, grapes, wine: 5%, hazelnuts: 5%, honeydews: 90%, kumquat: 2.5%, lemons: 2.5%, lettuce: 15%, lima beans: 40%, lime: 2.5%, okra: 45%, onions: 5%, oranges, 10%, peanuts: 20%, pears: 2.5%, green peas (fresh & succulent): 50%, pecans: 20%, peppers (all): 30%, pistachios: 55%, potatoes: 15%, pummelo: 2.5%, pumpkins: 25%, soybeans: 10%, spinach: 15%, squash: 25%, strawberries: 70%, sweet corn: 50%, tangerines: 2.5%, tomatoes: 45%, walnuts: 25%, and watermelons: 20%. The acute dietary assessment also used the following maximum PCT estimates for some of the new uses: apples: 55%, avocados: 50%, nectarines: 65%, peaches: 35%, and pomegranates: 60%.

The following average PCT estimates for bifenthrin were used to refine the chronic dietary risk assessment for the following crops: Almonds: 25%, artichoke: 30%, green beans (fresh & succulent): 55%, blueberries (all bushberries): 10%, broccoli: 15%, Brussel sprouts: 1%, cabbage: 30%, caneberries: 45%, canola: 10%, cantaloupes: 50%, carrots: 2.5%, cauliflower: 1%, celery: 10%, citrus (all others): 1%, corn: 5%, cotton: 15%, cucumbers: 20%, dry beans/peas: 2.5%, eggplant: 25%, grapefruit: 1%, grapes, juice: 2.5%, grapes, table: 1%, grapes, wine: 2.5%, hazelnuts: 1%, honeydews: 25%, kumquat: 1%, lemons: 1%, lettuce: 10%, lima beans: 20%, lime: 1%, okra: 25%, onions: 2.5%, oranges, 1%, peanuts: 10%, pears: 1%, green peas (fresh & succulent): 30%, pecans: 10%, peppers (all): 20%, pistachios: 35%, potatoes: 10%, pummelo: 1%, pumpkins: 15%, soybeans: 5%, spinach: 2.5%, squash: 20%, strawberries: 55%, sweet corn: 40%, tangerines: 1%, tomatoes: 25%, walnuts: 15%, and watermelons: 15%. The chronic dietary assessment also used the following maximum PCT estimates for some of the new uses: apples: 50%, avocados: 50%, nectarines: 65%, peaches: 35%, and pomegranates: 60%.

A default of 100% CT was used for all livestock and game commodities, freshwater finfish, and all other registered uses where no maximum/average PCT estimates were available. All other commodities included for depicting food handling establishment (FHE) uses were refined with the upper bound estimate of 4.65% for non-fumigant treatments made in FHEs.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS),

proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute 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 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

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 are taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

EPA used the limit of solubility as the drinking water input, *i.e.*, the maximum possible residues that could occur in drinking water based on the chemical properties of the compound. EPA used the modeled EDWCs directly in the dietary exposure model to account for the contribution of bifenthrin residues in drinking water as follows: 0.014 ppb was used in the acute assessment and 0.014 ppb was used in the chronic assessment.

**3. From non-dietary exposure.** The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Bifenthrin is currently registered for the following uses that could result in residential exposures: Lawns/turf, indoor environments, gardens/trees, pets (dog shampoo), termiticide and indoor/outdoor surface treatment for various residential and commercial premises.

EPA assessed residential exposure using the following assumptions. There is the potential for residential handler and post-application exposures from the use of bifenthrin. These exposures were assessed using the 2012 Residential SOPs and submitted chemical-specific residue data [bifenthrin-specific turf transferable residue (TTR; liquid and granular) and dislodgeable foliar residue (DFR; liquid) data are available]. EPA did not quantitatively assess the outdoor residential handler uses in/around home foundations, outdoor impervious surfaces, wood piles/structures and fence posts. Residential handler exposure assessments were performed for adult homeowners applying bifenthrin ready-to-use products (aerosol, hose-end sprayers and dog shampoos); mixing/loading/applying liquid concentrates; loading/applying granular formulations and applying dust formulations. The application rates for these uses that were quantitatively assessed are equal to or higher than those outdoor uses and thus are protective of the outdoor uses. Dermal and inhalation risk estimates were combined in this assessment because the toxicological effects for these exposure routes were the same. A total aggregate risk index (ARI) was used because the levels of concern (LOCs) for dermal exposure (100) and inhalation exposure (30) are different. ARIs of less than 1 are risk estimates of concern. The

ARIs were calculated as follows.  $Aggregate\ Risk\ Index\ (ARI) = 1 + [(Dermal\ LOC \div Dermal\ MOE) + (Inhalation\ LOC \div Inhalation\ MOE)]$ . All exposures are short-term in nature. There are no dermal or inhalation risk estimates of concern for residential handlers for the registered uses of bifenthrin.

Post-application exposure was assessed for broadcast applications to turf, gardens/trees, indoor environments (carpets and hard floor) and treated pets. Residential post-application exposures are expected to be short-, intermediate- or long-term in duration. Because the single dose and repeat dosing bifenthrin studies show that repeat exposures do not result in lower points of departure, the residential assessments are conducted as a series of acute exposures and the same endpoint is used regardless of duration. Therefore, the acute/single day residential post-application assessments are protective of expected longer-term exposures. Dermal and incidental oral risk estimates were combined because the toxicological effects for these exposure routes were similar [combined Margin of Exposure (MOE) approach used since LOCs are the same].

There were some residential post-application risk estimates of concern identified previously in Registration Review. Specifically, dermal post-application risks were identified for a liquid formulation product with a maximum application rate of 2.3 lb ai/A, and risks were identified for episodic ingestion of granules at application rates greater than 0.34 lb ai/A. As a result, during Registration Review, some bifenthrin labels were amended or canceled to address these risk concerns. The product label for the liquid formulation with the high application rate of 2.3 lb ai/A, which was canceled as of July 2021 (EPA Reg. #279-3152), was never commercialized. Because that product was never sold or distributed, there are no exposures from that product for consideration in the aggregate risk assessment. In addition, 25 granular products were either canceled or amended to require watering in of the product after application when application rates were greater than 0.34 lb ai/A. Although these label changes reduce the risks from ingestion of granules, that use is not included in the aggregate assessment because it is considered an episodic event and not a routine behavior.

The following residential exposure scenarios were selected for aggregation and represent the worst-case risk estimates: Adults contacting treated gardens (dermal exposure); children 1 to

<2 years old contacting treated turf (dermal and incidental oral exposure at the 0.23 lb ai/A rate); children 6 to <11 years old contacting treated gardens (dermal exposure); and children 11 to 16 years old golfing on treated turf (dermal exposure).

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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 has determined that the pyrethroids and pyrethrins share a common mechanism of toxicity (<http://www.regulations.gov>; EPA–HQ–OPP–2008–0489–0006). As explained in that document, the members of this group share the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. In 2011, after establishing a common mechanism grouping for the pyrethroids and pyrethrins, the Agency conducted a cumulative risk assessment (CRA) which is available at <http://www.regulations.gov>; EPA–HQ–OPP–2011–0746. In that document, the Agency concluded that cumulative exposures to pyrethroids (based on pesticidal uses registered at the time the assessment was conducted) did not present risks of concern. For information regarding EPA’s efforts to evaluate the risk of exposure to this class of chemicals, refer to <https://www.epa.gov/ingredients-used-pesticide-products/pyrethrins-and-pyrethroids>.

Since the 2011 CRA, for each new pyrethroid and pyrethrin use, the Agency has conducted a screen to evaluate any potential impacts on the CRA prior to registration of that use. A new turf use for the pyrethroid, tau-fluvalinate, was assessed after completion of the cumulative, which did impact the worst-case non-dietary risk estimates identified in the 2011 CRA for the turf scenario (Memo, DeLeon, H., D450820, 12/16/2019). However, the overall finding (*i.e.*, that the pyrethroid cumulative risk is below the Agency’s level of concern) did not change upon registration of this new use.

To account for the additional uses requiring tolerances in this rule, the Agency has conducted an additional screen, taking into account all previously approved uses and these proposed new uses. The additional uses will not significantly impact the cumulative assessment because dietary exposures make a minor contribution to total pyrethroid exposure relative to residential exposures in the 2011 cumulative risk assessment. Therefore, the results of the 2011 CRA are still valid and there are no cumulative risks of concern for the pyrethroids/ pyrethrins.

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

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

2. *Prenatal and postnatal sensitivity.* Bifenthrin has been evaluated for potential developmental effects in the rat (following gavage and dietary administration) and in the rabbit (gavage administration). Maternal toxicity included neurological effects (tremors in rats and rabbits; head and forelimb twitching in rabbits). There were no developmental effects of biological significance in either species. The registrant submitted a Developmental Neurotoxicity (DNT) study, which establishes a clear NOAEL for the adult and offspring toxicity. The NOAEL in adults and offspring is similar in magnitude, and the LOAELs are based on the clinical signs of neurotoxicity (dams had tremors and convulsions, offspring had increased grooming counts). Based on targeted testing in the DNT study for common endpoints for bifenthrin, there was no increase in sensitivity in rat pups. However, the Agency has reviewed existing pyrethroid data and concludes that the DNT is not a particularly sensitive study for comparing the sensitivity of young and adult animals to pyrethroids. Some literature studies indicated susceptibility for other pyrethroids, but in context, these studies were

conducted at relatively high doses, which may not reflect environmental exposures. The reproductive toxicity of bifenthrin was examined in a 2-generation reproduction dietary study in the rat. Tremors were noted only in females of both generations, with one parental generation rat observed to have clonic convulsions, and no observed effects in the offspring. Overall, there is no indication of increased juvenile sensitivity specifically to bifenthrin.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings.

i. The toxicity database for bifenthrin is complete.

ii. 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 in 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 was no evidence that bifenthrin resulted in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. Previously, however, EPA retained a FQPA safety factor of 3X to account for concerns about pharmacokinetic (PK) differences between adults and children. The Agency has re-evaluated the need for an FQPA Safety Factor for human health risk assessments for pyrethroid pesticides based on a review of the available guideline and literature studies as well as data from the Council for the Advancement of Pyrethroid Human Risk Assessment (CAFHRA) program. That recent data, including human physiologically based pharmacokinetic (PBPK) models as well as *in vivo* and *in vitro* data on protein binding, enzyme ontogeny, and metabolic clearance, support the conclusion that the PK contribution to the FQPA safety factor can be reduced to 1X for all populations.

iv. There are no residual uncertainties identified in the exposure databases.

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 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.

#### *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 exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to bifenthrin will occupy 15% of the aPAD for infants (<1 year old), the population group receiving the greatest exposure. The acute aggregate risk assessment combines exposures to bifenthrin in food and drinking water only and is equivalent to the acute dietary assessment. There are no acute aggregate risks estimates of concern.

2. *Chronic risk.* The chronic (food and drinking water) exposure assessment for bifenthrin was conducted solely for the purpose of obtaining an average dietary exposure estimate for use in the aggregate assessment. The population subgroup with the highest average dietary exposure estimate is children 1 to 2 years old (0.000189 mg/kg/day).

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 an aggregate MOE of 520 for adults (treated gardens). The short-term aggregate assessment for children 1 to less than 2 years old resulted in an MOE of 170 (treated turf at 0.23 lb ai/A). The short-term aggregate assessment for children 6 to less than 11 years old and children 11 to 16 years old resulted in MOEs of 1,600 (treated gardens) and 7,600 (golfing), respectively. Because EPA's level of concern for bifenthrin is an MOE of 100 or lower, these MOEs 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). While there is potential intermediate-term residential exposure, because the single dose and repeat dosing bifenthrin studies show that repeat exposures do not result in lower points of departure, the residential assessments are conducted as a series of acute exposures and the same endpoint is used regardless of duration. Therefore, the short-term aggregate assessment is considered protective of any intermediate-term exposures.

5. *Aggregate cancer risk for U.S. population.* EPA has concluded that the acute reference dose (RfD) will adequately account for all repeated exposures, including carcinogenicity, which could result from exposure to bifenthrin.

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.

## **IV. Other Considerations**

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (gas chromatography with an electron capture detector (GC/ECD) analyses for determining bifenthrin residues in both plant and livestock commodities) 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](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 any MRLs for bifenthrin in or on apple, wet pomace; avocado; fruit, pome, group 11-10; peach, or pomegranate. The following U.S. tolerances being established are harmonized with the Codex MRLs, which are identified in parentheses: Caneberry subgroup 13-07A at 1 ppm (blackberry, dewberries and raspberries); fruit, citrus, group 10-10 at 0.05 ppm (citrus fruit); and nut, tree, group 14-12 at 0.05 ppm (tree nuts). The U.S. tolerance for pepper/eggplant subgroup 8-10B at 0.5 ppm is harmonized with the Codex MRL on pepper. It is not possible to harmonize with the Codex MRLs of all commodities in the subgroup, including eggplant at 0.3 ppm and dried chili peppers at 5 ppm.

The Codex has established an MRL for bifenthrin in or on grape at 0.3 ppm. The Agency is establishing the tolerance in or on fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.3 ppm (rather than at 0.2 ppm, the existing U.S. tolerance on grape) to harmonize with the Codex MRL on grape.

The Canadian MRL for bifenthrin in or on pear is 0.9 ppm and there are no Codex MRLs for the commodities in the pome fruit crop group. EPA is establishing the U.S. tolerance for fruit, pome, group 11-10, except mayhaw at 0.9 ppm (rather than at the request level of 0.70 ppm based on submitted residue data and the existing U.S. tolerance for



pear) to harmonize with the Canadian MRL.

EPA is establishing the tolerance for tomato subgroup 8–10A at 0.3 ppm (rather than at 0.15 ppm, the existing U.S. tolerance on tomato) to harmonize with the Codex MRL of 0.3 ppm in/on tomato. Additionally, EPA is establishing the tolerance for *Brassica*, leafy greens, subgroup 4–16B at 4 ppm (rather than at 3.5 ppm, the existing U.S. tolerance on *Brassica*, leafy greens, subgroup 5B) to harmonize with the Codex MRL of 4 ppm in/on mustard greens.

It is not possible to harmonize the U.S. tolerance for Berry, low growing, subgroup 13–07G at 3 ppm with the Codex MRL for strawberry at 1 ppm. Reducing the U.S. tolerance would put U.S. growers at risk of having violative residues despite legal use of the pesticide according to the label.

#### C. Revisions to Petitioned-For Tolerances

EPA is establishing the tolerance at different levels than requested for: Apple, wet pomace; avocado; berry, low growing, subgroup 13–07G; *Brassica*, leafy greens, subgroup 4–16B; caneberry subgroup 13–07A; fruit, pome, group 11–10, except mayhaw; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F; peach subgroup 12–12B; pepper/eggplant subgroup 8–10B; pomegranate; sunflower (crop subgroup 20B) and tomato subgroup 8–10A.

All trailing zeroes have been removed from the proposed tolerances to be consistent with Organization for Economic Cooperation and Development (OECD) Rounding Class Practice. In addition, the proposed apple, wet pomace tolerance of 1.3 ppm has been established at 1.5 ppm because the value determined is rounded following the OECD rounding class practice.

To harmonize with the applicable international MRLs, the tolerances for fruit, pome, group 11–10, except mayhaw; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F; and tomato subgroup 8–10A were established at higher limits than what was proposed.

The petitioner withdrew the change to the use pattern that would have necessitated the change to the tolerance for *Brassica*, leafy greens, subgroup 4–16B from 3.5 ppm to 15 ppm. EPA is establishing the tolerance for *Brassica*, leafy greens, subgroup 4–16B at 4 ppm, based on the crop group conversion of the established tolerance on *Brassica*, leafy greens, subgroup 5B and adjusting it to harmonize with the Codex MRL for mustard greens.

The commodity definition for sunflower (crop subgroup 20B) has been revised to sunflower subgroup 20B and the proposed tolerance at 0.01 has been established at 0.05 based on the current enforcement method limit of quantitation (LOQ).

#### D. International Trade Considerations

In this rule, EPA is establishing a lower tolerance for bifenthrin residues in or on groundcherry than the current tolerance. The current tolerance for groundcherry is 0.5 ppm, but groundcherry is a commodity in the proposed crop group expansion from tomato to tomato subgroup 8–10A, for which EPA is establishing a new tolerance in this rulemaking at 0.3 ppm. As a result, EPA intends for the allowable residues on groundcherry to be reduced. As discussed in EPA's crop grouping rulemaking, EPA has determined that groundcherry is similar to tomatoes and appropriately categorized in subgroup 8–10A. See 72 FR 69150 (Dec. 7, 2007). Based on residue data supporting the 0.3 ppm tolerance for subgroup 8–10A and the similarity of groundcherry to tomatoes, EPA concludes that it is appropriate to reduce the tolerance on groundcherry as well.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of the changes to these tolerances in order to satisfy its obligations under the Agreement. In addition, the SPS Agreement requires that Members provide a "reasonable interval" between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. Accordingly, EPA is establishing an expiration date for the existing tolerance to allow this tolerance to remain in effect for a period of six months after the effective date of this final rule. After the six-month period expires, this tolerance will be reduced or revoked, as indicated in the regulatory text, and allowable residues on groundcherry must conform to the tolerance for subgroup 8–10A.

This reduction in tolerance level is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance level is supported by available residue data.

#### V. Conclusion

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 apple, wet pomace at 1.5 ppm; avocado at 0.5 ppm; berry, low growing, subgroup 13–07G at 3 ppm; *Brassica*, leafy greens, subgroup 4–16B at 4 ppm; caneberry subgroup 13–07A at 1 ppm; fruit, citrus, group 10–10 at 0.05 ppm; fruit, pome; group 11–10, except mayhaw at 0.9 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.3 ppm; nut, tree, group 14–12 at 0.05 ppm; peach subgroup 12–12B at 0.7 ppm; pepper/eggplant subgroup 8–10B at 0.5 ppm; pomegranate at 0.5 ppm; sunflower subgroup 20B at 0.05 ppm; and tomato subgroup 8–10A at 0.3 ppm.

The following tolerances are removed as unnecessary due to the establishment of the above tolerances: *Brassica*, leafy greens, subgroup 5B at 3.5 ppm; caneberry subgroup 13A at 1.0 ppm; eggplant at 0.05 ppm; fruit, citrus, group 10 at 0.05 ppm; grape at 0.2 ppm; nut, tree, group 14 at 0.05 ppm; okra at 0.50 ppm; pear at 0.5 ppm; pepino at 0.5 ppm; pepper, bell at 0.5 ppm; pepper, nonbell at 0.5 ppm; pistachio at 0.05 ppm; strawberry at 3.0 ppm; tomato at 0.15 ppm; and turnip, greens at 3.5 ppm.

Additionally, the following Section 18 time-limited tolerances are removed as unnecessary due to the establishment of the above permanent tolerances: Apple at 0.5 ppm; avocado at 0.50 ppm; nectarine at 0.5 ppm; peach at 0.5 ppm; and pomegranate at 0.50 ppm.

Finally, EPA is setting a six-month expiration date for the current groundcherry tolerance at 0.5 ppm.

#### VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to petitions 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 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), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). 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 on the basis of a petition under FFDCA section 408(d), 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).

**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: November 10, 2021.

**Marietta Echeverria,**  
*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

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

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

■ 2. Amend § 180.442 by:

- a. In the table in paragraph (a)(1)
  - i. Adding in alphabetical order the commodities: “Apple, wet pomace”; “Avocado”; “Berry, low growing, subgroup 13–07G”; “*Brassica*, leafy greens, subgroup 4–16B”;
  - ii. Removing the commodities: “*Brassica*, leafy greens, subgroup 5B”; “Caneberry subgroup 13A”;

- iii. Adding in alphabetical order the commodity “Caneberry subgroup 13–07A”;
- iv. Removing the commodities “Eggplant”; “Fruit, citrus, group 10”;
- v. Adding in alphabetical order the commodities “Fruit, citrus, group 10–10”; “Fruit, pome, group 11–10, except mayhaw”; “Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F”;
- vi. Removing the commodity “Grape”;
- vii. Revising the entry for “Groundcherry”
- viii. Removing the commodity “Nut, tree, group 14”;
- ix. Adding in alphabetical order the commodity “Nut, tree, group 14–12”;
- x. Removing the commodity “Okra”;
- xi. Adding in alphabetical order the commodity “Peach subgroup 12–12B”
- xii. Removing the commodities “Pear”; “Pepino”; “Pepper, bell”; “Pepper, nonbell”;
- xiii. Adding in alphabetical order the commodity “Pepper/eggplant subgroup 8–10B”;
- xiv. Removing the commodity “Pistachio”
- xv. Adding in alphabetical order the commodity “Pomegranate”;
- xvi. Removing the commodity “Strawberry”;
- xvii. Adding in alphabetical order the commodity “Sunflower subgroup 20B”;
- xviii. Removing the commodity “Tomato”;
- xix. Adding in alphabetical order the commodity “Tomato subgroup 8–10A”;
- and
- xx. Removing the commodity “Turnip, greens”.
- b. Remove and reserve paragraph (b).  
The additions and revisions read as follows.

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

(a)(1) \* \* \*

Commodity	Parts per million
Apple, wet pomace	1.5
Avocado	0.5
Berry, low growing, subgroup 13–07G	3
<i>Brassica</i> , leafy greens, subgroup 4–16B	4
Caneberry subgroup 13–07A	1

Commodity	Parts per million
Fruit, citrus, group 10–10	0.05
Fruit, pome, group 11–10, except mayhaw	0.9
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.3
Groundcherry <sup>2</sup>	0.5
Nut, tree, group 14–12	0.05
Peach subgroup 12–12B	0.7
Pepper/eggplant subgroup 8–10B	0.5
Pomegranate	0.5
Sunflower subgroup 20B	0.05
Tomato subgroup 8–10A	0.3

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

<sup>2</sup> This tolerance expires on June 1, 2022.

\* \* \* \* \*  
 [FR Doc. 2021–25091 Filed 11–30–21; 8:45 am]  
**BILLING CODE 6560–50–P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 272**

[EPA–R06–RCRA–2020–0261; FRL–9240–02–R6]

**Louisiana: Incorporation by Reference of Approved State Hazardous Waste Management Program**

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

**ACTION:** Final rule.

**SUMMARY:** This rule codifies in the regulations the prior approval of Louisiana’s hazardous waste management program and incorporates by reference authorized provisions of the State’s statutes and regulations. The Environmental Protection Agency (EPA) uses the regulations entitled “Approved State Hazardous Waste Management Programs” to provide notice of the authorization status of State programs and to incorporate by reference those provisions of the State statutes and regulations that are authorized and that EPA will enforce under the Solid Waste Disposal Act, commonly referred to as the Resource Conservation and Recovery Act (RCRA). The EPA previously provided notices and

opportunity for comments on the Agency’s decisions to authorize the State of Louisiana program and the EPA is not now reopening the decisions, nor requesting comments, on the Louisiana authorizations as previously published in the **Federal Register** documents specified in Section I.C of this final rule document.

**DATES:** This regulation is effective January 3, 2022. The Director of the Federal Register approves this incorporation by reference as of January 3, 2022, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA–R06–RCRA–2020–0261. All documents in the docket are listed in the <https://www.regulations.gov> index. Although listed in the index, some of the information is not publicly available. *e.g.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically through <https://www.regulations.gov>. For alternative access to docket materials, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** Alima Patterson, EPA Region 6 Regional Authorization/Codification Coordinator,

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**SUPPLEMENTARY INFORMATION:**

**I. Incorporation by reference**

*A. What is codification?*

Codification is the process of placing a State’s statutes and regulations that comprise the State’s authorized hazardous waste management program into the Code of Federal Regulations (CFR). Section 3006(b) of RCRA, as amended, allows the EPA to authorize State hazardous waste management programs to operate in lieu of the Federal hazardous waste management regulatory program. The EPA codifies its authorization of State programs in 40 CFR part 272 and incorporates by reference State statutes and regulations that the EPA will enforce under sections 3007 and 3008 of RCRA and any other applicable statutory provisions.

The incorporation by reference of State authorized programs in the CFR should substantially enhance the public’s ability to discern the current status of the authorized State program and State requirements that can be