enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 62

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Landfills, Methane, Ozone, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Deborah Jordan,

Acting Regional Administrator, Region IX.

Note: The EPA fully approved Arizona's state plan on August 30, 2019, when the EPA signed an unpublished hard copy of a Notice of Final Rulemaking that is identical to this electronically signed notice. Arizona's state plan will become effective on the date set forth herein.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 62 as follows:

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

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

Subpart D—Arizona

■ 2. Section 62.600 is revised to read as follows:

§ 62.600 Identification of plan.

(a) The Arizona Department of Environmental Quality submitted on June 17, 1997, and June 29, 1999, the State of Arizona's Section 111(d) Plan for Existing Municipal Solid Waste Landfills.

(b) Control of landfill gas emissions from existing municipal solid waste landfills, submitted by the Arizona Department of Environmental Quality on July 24, 2018, to implement 40 CFR part 60, subpart Cf. The Plan includes the regulatory provisions cited in paragraph (d) of this section, which the EPA incorporates by reference.

(c) After August 27, 2020, the substantive requirements of the municipal solid waste landfills state plan are contained in paragraph (b) of this section and owners and operators of municipal solid waste landfills in Arizona must comply with the requirements in paragraph (b) of this section.

(d)(1) The material incorporated by reference in this section was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies at the EPA Region 9 office, 75 Hawthorne Street, San Francisco, California 94105, 415–947–8000 or from the source listed in this paragraph (d). Copies may be inspected at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(2) State of Arizona, Arizona Secretary of State, 1700 W Washington St Floor 7, Phoenix, AZ 85007.

(i) Title 18 Arizona Administrative Code, Title 2. Department of Environmental Quality—Air Pollution Control:

(A) Article 7. Existing Stationary Source Performance Standards R18–2–731 Standards of Performance for Existing Municipal Solid Waste Landfills, effective August 10, 2018.

(B) Article 9. New Source Performance Standards R18–2–901 Standards of Performance for New Stationary Sources, paragraph (80), effective August 10, 2018.

(ii) [Reserved]

■ 3. Section 62.601 is revised to read as follows:

§ 62.601 Identification of sources.

(a) The plan applies to all existing municipal solid waste landfills for which construction, reconstruction, or modification was commenced before May 30, 1991, as described in 40 CFR part 60, subpart Cc.

(b) The plan in § 62.600(b) applies to all existing municipal solid waste landfills under the jurisdiction of the Arizona Department of Environmental Quality for which construction, reconstruction, or modification was commenced on or before July 17, 2014.

■ 4. Section 62.602 is revised to read as follows:

§ 62.602 Effective date.

(a) The effective date of EPA approval of the plan is November 19, 1999.

(b) The effective date of the plan submitted on July 24, 2018, by the Arizona Department of Environmental Quality for municipal solid waste landfills is August 27, 2020.

[FR Doc. 2020–15499 Filed 7–27–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0683; FRL–10009–45]

Permethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective July 28, 2020. Objections and requests for hearings must be received on or before September 28, 2020 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–2018–0683, 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 note that due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael 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 EPA's tolerance regulations at 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.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2018–0683 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 September 28, 2020. 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–2018–0683, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 18, 2019 (84 FR 9737) (FRL–9989–71), 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 8E8703) by IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested to establish tolerances in 40 CFR 180.378 for the combined residues of the insecticide *cis-* and *trans-*permethrin isomers [*cis-*(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate] and [*trans-*(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate] in or on the following agricultural commodities: Celtuce at 5.0 parts per million (ppm); cherry subgroup 12–12A at 4.0 ppm; fennel, Florence at 5.0 ppm; leaf petiole vegetable subgroup 22B at 5.0 ppm; peach, subgroup 12–12B at 2.0 ppm; tea, plucked leaves at 20 ppm; vegetable, tuberous and corm, subgroup 1C at 0.05 ppm; and a regional tolerance in/on fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2.0 ppm. Additionally, the petition requested, upon approval of the above tolerances, to remove the existing tolerances in 40 CFR 180.378 in/on the following agricultural commodities: Cherry, sweet at 4.0 ppm; cherry, tart at 4.0 ppm; leaf petioles subgroup 4B at 5.0 ppm; peach at 1.0 ppm; and potato at 0.05 ppm. That document referenced a summary of the petition prepared by FMC, 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 petition, EPA is establishing 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 permethrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with permethrin 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.

Behavioral changes and neurotoxic effects, which are characteristic of Type I pyrethroids, were the primary effects seen in most toxicity studies. In addition, permethrin has been re-classified from ''Likely to be Carcinogenic to Humans'' to ''Suggestive Evidence of Carcinogenic Potential'' based on lung adenomas in female mice. Based on a re-evaluation of available data, EPA concluded that a non-linear approach to assessing

carcinogenicity would be appropriate because the selected acute reference dose would be protective of potential carcinogenicity. A complete discussion of the toxicological profile for permethrin and the Agency's cancer conclusion as well as specific information on the studies received and the nature of the adverse effects caused by permethrin 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 document titled ''*Permethrin: Human Health Risk Assessment for New Use on ''Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit, Subgroup 13–07F''; Multiple Crop Group Conversions/Expansions; and the Establishment of a Tolerance without a U.S. Registration for Tea, AND the Revised Draft Risk Assessment (DRA) for Registration Review*'' (hereinafter ''Permethrin Human Health Risk Assessment'') in docket ID number EPA–HQ–OPP–2018–0683 in *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 the NOAEL are the LOAEL are identified. 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 permethrin used for human risk assessment can be found in the Permethrin Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to permethrin, EPA considered exposure under the petitioned-for tolerances as well as all existing permethrin tolerances in 40 CFR 180.378. EPA assessed dietary exposures from permethrin 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 permethrin. In estimating acute dietary exposure, EPA used 2003–2008 food consumption information from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). 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 permethrin because repeated exposure does not result in a point of departure 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 permethrin, a highly refined chronic dietary exposure assessment was conducted to calculate average dietary (food and drinking water) exposure estimates to support the permethrin aggregate risk assessment. The average assessment was refined using point estimates derived from PDP monitoring data, field trial data, PCT data, and empirical processing factors.

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.

Since the last permethrin risk assessment, the carcinogenic potential of permethrin was reevaluated in response to new information submitted. Based on the review of these data, permethrin is now classified as ''Suggestive Evidence of Carcinogenic Potential'' and quantification of risk using a non-linear approach (*i.e.,* reference dose (RfD)) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to permethrin. A separate cancer dietary exposure and risk assessment is not required.

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

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

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area, 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: Apples (10%); asparagus (45%); broccoli (15%); cabbage (30%); cantaloupes (15%); cauliflower (20%); celery (90%); cherries (15%); corn (2.5%); cucumbers (10%); garlic (50%); hazelnuts (2.5%); lettuce (65%); onions (25%); peaches (20%); pears (10%);

peppers (20%); potatoes (10%); pumpkins (20%); soybeans (2.5%); spinach (75%); squash (20%); sweet corn (15%); tomatoes (10%); and watermelons (15%). 100 PCT was used for the remaining commodities.

The following average PCT estimates were used in the chronic dietary exposure assessment for the following crops that are currently registered for permethrin: Apples (5%); artichoke (35%); asparagus (30%); broccoli (10%); cabbage (15%); cantaloupes (10%); cauliflower (10%); celery (60%); cherries (10%); corn (1%); cucumbers (5%); garlic (20%); hazelnuts (2.5%); lettuce (50%); onions (15%); peaches (10%); pears (2.5%); peppers (10%); potatoes (10%); pumpkins (15%); soybeans (1%); spinach (55%); squash (10%); sweet corn (10%); tomatoes (5%); and watermelons (10%). Additionally, a PCT value of 100% from almond was used for all livestock commodities since almonds have the highest PCT estimate of the commodities that may be fed to livestock. 100 PCT was used for the remaining commodities.

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 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 permethrin 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 permethrin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of permethrin. 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.*

Using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW) models, EPA calculated the estimated drinking water concentrations (EDWCs) of permethrin for acute and chronic exposures in surface water. Residues are not expected to reach groundwater due to permethrin's high partition coefficient (K_d). EPA used the modeled EDWCs directly in the dietary exposure model to account for the contribution of permethrin residues in drinking water as follows: 10.0 ppb was used in the acute assessment; 1.60 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).

Permethrin is currently registered for the following uses that could result in residential exposures: Control of insects in indoor and outdoor residential sites, including use indoors as a direct spot treatment (with some residential site restrictions), crack and crevice application, aerosol space spray, and total release fogger. Outdoor applications can be made as a direct or spot treatment to buildings/household perimeters, landscaping, or lawns via aerosol cans, handheld equipment, and trigger sprays. EPA assessed residential exposure using the following assumptions: Several permethrin products require personal protective equipment (PPE) to be worn by applicators. As such, EPA assumes those products are not used by homeowners, so exposures from those products have been considered only for residential post-application exposure assessment. Permethrin product labels with residential use sites that do not require specific clothing (*e.g.,* long-sleeved shirt/long pants) and/or PPE, have been considered in the residential handler assessment. Residential handler exposure assessments were performed for adult homeowners applying permethrin dusts/powders, dips, ready-to-use products, and pump/trigger spray products to cats and dogs. For spot-on applications to pets, inhalation exposure is negligible. Since there is no dermal hazard for permethrin, the residential handler assessment includes only inhalation exposures. All exposure scenarios are short-term in nature.

As no dermal hazard has been identified for permethrin, a quantitative post-application dermal assessment has not been conducted. Short-term post-application inhalation is expected for adults. The short-term post-application exposure scenarios for children 1 to less than 2 years old and 3–6 years old (hand-to-mouth and inhalation exposures) were combined for each lifestage. This combination should be considered a protective estimate of children's exposure. In order to combine these exposures, an aggregate risk index (ARI) was used since the LOCs for children's hand-to-mouth exposure (100) and inhalation exposure (30) are different. The target ARI is 1; therefore, ARIs of less than 1 are risk estimates of concern. The ARIs were calculated as follows.

Aggregate Risk Index (ARI) = 1 ÷ [(Incidental Oral LOC ÷ Incidental Oral MOE) + (Inhalation LOC ÷ Inhalation MOE)].

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–2011–0746–0045). 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–2011–0746–0003. 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. 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.

Prior to a final registration review decision for permethrin, the Agency will determine whether the 2011 CRA needs to be updated based on the availability of any new hazard, use, or exposure information that could potentially change the conclusions of or otherwise impact the 2011 CRA.

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.* There was no evidence of increased qualitative or quantitative susceptibility in guideline developmental toxicity studies in the rat and rabbit and a three-generation reproductive toxicity study in the rat. Maternal toxicity included neurological effects such as tremors in the rat and decreased body weights in the rat and rabbit. Increased post-implantation loss, decreased offspring size, and decreased ossification were observed in the studies, but all effects occurred at maternally toxic doses or above.

3. *Conclusion.* The Agency considers the FQPA SF as having two components, with 3x assigned to pharmacokinetic (PK) and 3x to pharmacodynamic (PD) differences. Previously, the Agency retained a 3x FQPA SF (1x for PD and 3x for PK differences) for children less than 6 years old based on concerns for PK differences between adults and children. EPA has re-evaluated the need for an FQPA SF 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 (CAPHRA) program. Because no new information of suitable quality was available on the age-related PD properties of the pyrethroids, the PD contribution to the FQPA safety factor remains at 1x. Regarding PK, 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 SF can be reduced to 1x for all populations. For further information about the Agency's determination to reduce this FQPA safety factor, please see Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review, which can be found at *https://www.epa.gov/ingredients-used-pesticide-products/2019-evaluation-fqpa-safety-factor-pyrethroids.* Therefore, the Agency concludes that the default 10x FQPA SF can be reduced to 1x for all populations for the pyrethroid pesticides.

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 permethrin will occupy 12% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* A chronic dietary endpoint has not been selected for permethrin because repeated exposure does not result in a point of departure lower than that resulting from acute exposure; therefore, the acute dietary risk assessment is protective of chronic dietary risk.

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).

Permethrin 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 permethrin.

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 ARIs of 80 for adults and 2.9 for children 1 to less than 2 years old.

Because EPA's level of concern for permethrin is an ARI of 1 or below, these ARIs 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). Because no intermediate-term adverse effect was identified, permethrin is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* As stated in Unit III.A., EPA has concluded that the acute reference dose (RfD) will adequately account for all repeated exposure/chronic toxicity, including carcinogenicity, which could result from exposure to permethrin. Based on the lack of acute risk at regulated levels of exposure, EPA concludes that exposure to permethrin will not pose an aggregate 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 permethrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate gas chromatography (GC) electron capture detection (GC/ECD) methods are available for enforcing tolerances of permethrin *per se* and are listed in PAM Vol. II (Section 180.378). Method I is a GC/ECD method for determining permethrin in plant matrices and has a limit of quantitation (LOQ) of 0.05 ppm for each isomer. Method II is a GC/ECD method for determining permethrin in animal matrices that has a LOQ of 0.01 ppm for each isomer. In addition, permethrin is completely recovered using FDA Multiresidue Methods (PAM Vol. I Sections 302 and 304).

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 permethrin in or on celtuce, Swiss chard or Florence fennel. Therefore, harmonization is not an issue for these commodities.

The Codex has established MRLs for permethrin in or on tea, green, black (black, fermented and dried) at 20 ppm; potato at 0.05 ppm; and gooseberry and grapes at 2 ppm which are the same as the U.S. tolerances being established by this document and are therefore harmonized.

The Codex has established MRLs for permethrin in or on stone fruit at 2 ppm. The U.S. tolerance for peach subgroup 12–12B is harmonized with the Codex MRL. Harmonization of the U.S. tolerance for cherry subgroup 12–12A at 4 ppm is not possible because the U.S. tolerance is higher. Reducing the U.S. tolerance could cause U.S. growers to have violative residues despite legal use of permethrin.

The Codex has established MRLs for permethrin in or on celery at 2 ppm. This MRL is lower than the tolerance of 5 ppm being established for permethrin in or on leaf petiole vegetable subgroup 22B in the United States. Harmonization is not feasible because the tolerance is based on field trial data that resulted in residues that necessitated the higher limit.

C. Revisions to Petitioned-For Tolerances

All trailing zeroes have been removed from the proposed tolerances to be consistent with Organization for Economic Cooperation and Development (OECD) Rounding Class Practice.

A tolerance is currently established for residues of permethrin in/on the leaf petioles subgroup 4B at 5.0 ppm, which includes Swiss chard. Crop subgroup 4B is being converted to the leaf petiole vegetable subgroup 22B, which does not include Swiss chard. Therefore, the Agency is establishing an individual tolerance of 5 ppm for Swiss chard based on the currently established tolerance for this commodity as part of crop subgroup 4B.

The commodity definition for Florence fennel has been revised to read fennel, Florence, fresh leaves and stalks.

V. Conclusion

Therefore, tolerances are established for residues of permethrin in or on celtuce at 5 ppm; cherry subgroup 12–12A at 4 ppm; fennel, Florence, fresh leaves and stalks at 5 ppm; leaf petiole vegetable subgroup 22B at 5 ppm; peach subgroup 12–12B at 2 ppm; Swiss chard at 5 ppm; tea, plucked leaves at 20 ppm; vegetable, tuberous and corm, subgroup 1C at 0.05 ppm; and a tolerance for regional registration for fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2 ppm.

Additionally, the following tolerances are removed as unnecessary due to the establishment of the above tolerances: Cherry, sweet at 4.0 ppm; cherry, tart at 4.0 ppm; leaf petioles subgroup 4B at 5.0 ppm; peach at 1.0 ppm; potato at 0.05 ppm.

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

The revised tolerance expression makes clear that the tolerances cover residues of permethrin and its metabolites and degradates, but that compliance with the tolerance levels will be determined by measuring only permethrin [(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate], as the sum of its *cis-* and *trans-* isomers in or on the commodity. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this 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: June 12, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends 40 CFR part 180 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 § 180.378:

■ a. Amend paragraph (a) by:

■ i. Revising the introductory text;

■ ii. In the table, adding, in alphabetical order, the commodities ''celtuce; cherry subgroup 12–12A'', ''fennel, Florence, fresh leaves and stalks'', ''leaf petiole vegetable subgroup 22B'', ''peach subgroup 12–12B'', ''Swiss chard'', ''tea, plucked leaves; and vegetable, tuberous and corm, subgroup 1C''; and

■ iii. In the table, removing the commodities ''cherry, sweet'', ''cherry, tart'', ''leaf petioles subgroup 4B'', ''peach'', and ''potato''.

■ b. Amend paragraph (c) by:

■ i. Revising the introductory text; and

■ ii. In the table, adding, in alphabetical order, the commodity ''fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F''.

The revisions and additions read as follows:

§ 180.378 Permethrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of permethrin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only permethrin [(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate], as the sum of its *cis*- and *trans*- isomers in or on the commodity.

Commodity	Parts per million
* * * * * * *	
Celtuce	5
Cherry subgroup 12–12A	4
* * * * * * *	
Fennel, Florence, fresh leaves and stalks	5
* * * * * * *	
Leaf petiole vegetable subgroup 22B	5
* * * * * * *	
Peach subgroup 12–12B	2
* * * * * * *	
Swiss chard	5
Tea, plucked leaves [1]	20
* * * * * * *	
Vegetable, tuberous and corm, subgroup 1C	0.05

Commodity	Parts per million
* * * * * * *	

[1] There are no United States registrations for use of permethrin on tea, plucked leaves as of July 28, 2020.

* * * * *

(c) Tolerances with regional registrations. Tolerances with regional registrations, as defined in § 180.1(l), are established for residues of permethrin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only permethrin [(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate], as the sum of its *cis*- and *trans*- isomers in or on the commodity.

Commodity	Parts per million
* * * * * * *	
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	2
* * * * * * *	

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[FR Doc. 2020–14419 Filed 7–27–20; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0135; FRL–10008–20]

Ethalfluralin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation decreases the tolerance for residues of ethalfluralin in or on potato. Gowan Company requested this tolerance modification under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 28, 2020. Objections and requests for hearings must be received on or before September 28, 2020, 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–2019–0135, 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 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.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2019–0135 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 September 28, 2020. 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–2019–0135, 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.