copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 21, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: December 2, 2019.

Chris Hladick,

Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart C—Alaska

■ 2. In § 52.70, the table in paragraph (e) is amended by:

■ a. Revising the entry for ''III.II.D. CAA Section 110 Infrastructure Certification Documentation and Supporting Documents''; and

■ b. Adding an entry for ''Infrastructure Requirements—2015 Ozone NAAQS'' at the end of the table.

The revision and addition read as follows:

§ 52.70 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED ALASKA NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanations
*	* *	*	*	* *
State of Alaska Air Quality Control Plan: Volume III. Appendices				
Section II. State Air Quality Control Program				
*	* *	*	*	* *
III.II.D. CAA Section 110 Infrastructure Certification Documentation and Supporting Documents.	Statewide	10/25/2018	12/23/2019, [Insert **Federal Register** citation].	
*	* *	*	*	* *
Infrastructure Requirements—2015 Ozone NAAQS.	Statewide	10/25/2018	12/23/2019, [Insert **Federal Register** citation].	Approves SIP for purposes of CAA section 110(a)(2)(A), (B), (C), (D)(i)(II), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M) for the 2015 Ozone NAAQS.

[FR Doc. 2019–27159 Filed 12–20–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0358; FRL–10001–86]

Fenpropathrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fenpropathrin in or on fuzzy kiwifruit. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on fuzzy kiwifruit. This regulation establishes a maximum permissible level for residues of fenpropathrin in or on this commodity. The time-limited tolerance expires on December 31, 2022.

DATES: This regulation is effective December 23, 2019. Objections and requests for hearings must be received on or before February 21, 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–2019–0358, is available at *https://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 *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 40 CFR part 180 through the Government Publishing Office's e-CFR site at *https://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp* and select ''Test Guidelines for Pesticides and Toxic Substances.''

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

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2019–0358 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before February 21, 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–2019–0358, by one of the following methods:

- *Federal eRulemaking Portal: https://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 *https://www.epa.gov/dockets.*

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance for residues of fenpropathrin, (alpha-cyano-3-phenoxy-benzyl 2,2,3,3 tetramethylcyclopropanecarboxylate), in or on fuzzy kiwifruit at 5 parts per million (ppm). This time-limited tolerance expires on December 31, 2022.

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

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

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

III. Emergency Exemption for Fenpropathrin on Fuzzy Kiwifruit and FFDCA Tolerances

According to the Alabama Department of Agriculture and Industries (ADAI), in 2017 brown marmorated stink bug (BMSB) damage was observed in a small block of nursery stock plants. This observation alerted the staff at the kiwi nursery to the potential of BMSB for the 2018 crop season. ADAI claimed that in 2018, BMSB severely damaged the kiwifruit crop, making it unmarketable. ADAI estimated losses as high as 50% for 2018 and projected 2019 losses to be over $1.6 million without the use requested under the section 18 emergency exemption. After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by

residues of fenpropathrin in or on fuzzy kiwifruit. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent, non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although this time-limited tolerance expires on December 31, 2022, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on fuzzy kiwifruit after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether fenpropathrin meets FIFRA's registration requirements for use on fuzzy kiwifruit or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of fenpropathrin by a State for special local needs under FIFRA section 24(c), nor does this tolerance by itself serve as the authority for persons in any State other than Alabama to use this pesticide on the applicable crops under FIFRA section 18, absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for fenpropathrin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of, and to make a determination on, aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerance for residues of fenpropathrin on fuzzy kiwifruit at 5 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerance follows.

A. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks.*

A summary of the toxicological endpoints for fenpropathrin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of November 28, 2012 (77 FR 70904) (FRL–9366–1).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenpropathrin, EPA considered exposure under the time-limited tolerance established by this action as well as all existing fenpropathrin tolerances in 40 CFR 180.466. EPA assessed dietary exposures from fenpropathrin in food as follows:

i. *Acute exposure.* Acute effects were identified for fenpropathrin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance level residues for some commodities and refined the assessment by incorporating distributions of field trial values and Pesticide Data Program (PDP) monitoring data for other commodities. EPA translated data from some commodities to other commodities according to EPA's guidance documents for translating monitoring data and field trial data. EPA also included estimates of percent crop treated in the assessment. For most processed commodities, EPA used the Agency's 2018 default processing factors for those commodities for which they were available. In some cases, EPA used empirical processing factors.

ii. *Chronic exposure.* Based on the available data for fenpropathrin, use of the acute endpoint and dose for risk assessment is protective for repeated dose exposure and risk. Therefore, only an acute dietary assessment was performed, which is considered protective of chronic dietary exposure.

iii. *Cancer.* Based on the data cited in Unit IV.A., EPA has concluded that fenpropathrin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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 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 Agency estimated the PCT for existing uses as follows: Apples, 15%; apricots 2.5%; blueberries, 2.5%; broccoli, 2.5%; Brussels sprouts, 10%; cabbage, 2.5%; cauliflower, 2.5%; cherries, 21%; cotton, 2.5%; cucumbers, 2.5%; grapefruit, 35%; grapes, 10%; nectarines, 9%; oranges, 35%; peaches, 9%; pears, 10%; plums, 2.5%; prune plums, 2.5%; squash, 2.5%; strawberries, 50%; tangerines, 15%; tomatoes, 10%; and watermelons, 2.5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 to 7 years. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency estimated the PCT for new uses as follows: 100% for fuzzy kiwifruit.

The Agency believes that the three conditions discussed in Unit IV.B1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which fenpropathrin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used water solubility limit at 25 °C in the dietary exposure analysis and risk assessment for fenpropathrin in drinking water. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

The water solubility limit of fenpropathrin at 25 °C is 10.3 parts per billion (ppb). The limit of solubility was directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 10.3 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fenpropathrin is not registered for any specific use patterns that would result in residential exposure.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: *https://www.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 is required to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. The agency has determined that the pyrethroids and pyrethrins share a common mechanism group (see *https://www.regulations.gov;* Docket ID EPA–HQ–OPP–2008–0489–0006). The members of this group share the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. The cumulative risk assessment for the pyrethroids/pyrethrins was published on Nov. 9, 2011 (USEPA, 2011a) and is available at *https://www.regulations.gov;* Docket ID EPA–HQ–OPP–2011–0746. No cumulative risks of concern were identified. This assessment was conservative and appropriate to address use expansions, such as this use on kiwifruit. For information regarding the EPA's efforts to evaluate the risk of exposure to pyrethroids, refer to *https://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.* After all of the chemical-specific interim decisions have been completed for the pyrethroid class of pesticides, an update of the cumulative risk assessment may be performed in association with registration review.

C. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* Evidence of increased qualitative or quantitative susceptibility of the offspring was not observed in any of the available animal testing guideline toxicity studies, including the developmental neurotoxicity study (DNT).

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the required 10X FQPA SF were reduced to 3X for children less than 6 years old. For the general population, and including children greater than 6 years old, EPA is reducing the FQPA SF to 1X. That decision is based on the following findings:

i. While the database is considered to be complete with respect to the guideline toxicity studies for fenpropathrin, EPA lacks additional data to fully characterize the potential for juvenile sensitivity to neurotoxic effects of pyrethroids. In light of the literature studies indicating a possibility of increased sensitivity in juvenile rats at high doses, EPA identified a need, and requested proposals for, additional non-guideline studies to evaluate the potential for sensitivity in juvenile rats. A group of pyrethroid registrants is currently conducting those studies. Pending the results of those studies, however, the available toxicity studies

for fenpropathrin can be used to characterize toxic effects including potential developmental and reproductive toxicity, immunotoxicity, and neurotoxicity. Acceptable developmental toxicity studies in rats and rabbits, reproduction studies in rats, neurotoxicity studies (acute, subchronic, and developmental) in rats, and immunotoxicity studies in rats are available. In addition, a route-specific dermal toxicity study is available, and the inhalation study has been waived.

ii. After reviewing the extensive body of data and peer-reviewed literature on pyrethroids, the Agency has reached a number of conclusions regarding fetal and juvenile sensitivity for pyrethroids. Based on an evaluation of over 70 guideline toxicity studies for 24 pyrethroids submitted to the Agency, including prenatal developmental toxicity studies in rats and rabbits, and pre- and postnatal multi-generation reproduction toxicity studies and DNTs in rats in support of pyrethroid registrations, there is no evidence that pyrethroids directly impact developing fetuses. None of the studies show any indications of fetal toxicity at doses that do not cause maternal toxicity.

iii. Increased susceptibility was seen in offspring animals in the DNT study with the pyrethroid zeta-cypermethrin (decreased pup body weights) and DNT and reproduction studies with another pyrethroid, beta-cyfluthrin (decreased body weights and tremors). However, the reductions in body weight and the other non-specific effects occur at higher doses than neurotoxicity, the effect of concern for pyrethroids. The available developmental and reproduction guideline studies in rats with zeta-cypermethrin did not show increased sensitivity in the young to neurotoxic effects. Overall, findings of increased sensitivity in juvenile animals in pyrethroid studies are rare. Therefore, the residual concern for the postnatal effects is reduced. High-dose LD50 studies (studies assessing what dose results in lethality to 50% of the tested population) in the scientific literature indicate that pyrethroids can result in increased quantitative sensitivity to juvenile animals. Examination of pharmacokinetic and pharmacodynamic data indicates that the sensitivity observed at high doses is related to pyrethroid age-dependent pharmacokinetics—the activity of enzymes associated with the metabolism of pyrethroids. Furthermore, a rat physiologically-based pharmacokinetic (PBPK) model predicts a 3-fold increase of pyrethroid concentration in juveniles' brains compared to adults at high doses. *In vitro* pharmacodynamic data and *in vivo* data indicate that adult and juvenile rats have similar responses to pyrethroids at low doses and therefore juvenile sensitivity is not expected at relevant environmental exposures. Further, data also show that the rat is a conservative model compared to the human based on species-specific pharmacodynamics of homologous sodium channel isoforms. The Agency has retained a 3X uncertainty factor to protect for exposures of children less than 6 years of age based on increased quantitative susceptibility seen in literature studies on pyrethroid pharmacokinetics (PKs), and the increased quantitative juvenile susceptibility observed in high dose studies in the literature.

iv. There are no residual uncertainties identified in the exposure databases. The Agency used tolerance level residues for some commodities and refined the assessment by incorporating distributions of field trial values and Pesticide Data Program (PDP) monitoring data for other commodities. EPA translated data from some commodities to other commodities according to EPA's guidance documents for translating monitoring data and field trial data. EPA also included estimates of percent crop treated in the assessment. For most processed commodities, EPA used the Agency's 2018 default processing factors for those commodities for which they were available. In some cases, EPA used empirical processing factors.

For this kiwifruit section 18 request, EPA updated the 2016 dietary exposure assessment by including kiwifruit. As residue data are not available for kiwifruit, the Agency translated grape PDP data to kiwifruit. For section 18 requests, the Agency assumes the proposed commodity will be treated to a level of 100% across the country. As a result, 100% crop treated was assumed for kiwifruit. EPA also made refinements to the residue data for dried cranberry, dried mango, and dried papaya. In the 2016 assessment, EPA used tolerance level residues for these commodities. For this section 18 request, EPA translated strawberry PDP data to dried cranberries, avocado field trial data to dried mango, and avocado field trial data to dried papaya. The Agency assumed 100% crop treated for the three dried commodities: Cranberry, mango, and papaya.

EPA made a conservative (protective) assumption in the water concentration used to assess exposure to fenpropathrin in drinking water. These assessments will not underestimate the exposure and risk posed by fenpropathrin.

D. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenpropathrin will occupy 99.5% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* A chronic dietary exposure assessment was not conducted because the acute endpoint adequately protects against chronic effects. There are no residential uses for fenpropathrin.

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). A short-term adverse effect was identified; however, fenpropathrin is not registered for any use patterns that would result in short-term residential exposure. Because there is no short-term residential exposure and acute dietary exposure has already been assessed under the appropriately protective aPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the acute dietary risk assessment for evaluating short-term risk for fenpropathrin.

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

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fenpropathrin is not expected to pose a cancer risk to humans.

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 fenpropathrin residues, including anticipated residues on fuzzy kiwifruit.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology utilizing gas chromatography with electron capture detector (GC/ECD), Residue Method Numbers RM–22–4 (plants) and RM–22A–1 (animals), is available to enforce the tolerance expression.

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

B. International Residue Limits

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

The Codex has not established an MRL for fenpropathrin on fuzzy kiwifruit.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of fenpropathrin, (alpha-cyano-3-phenoxy-benzyl 2,2,3,3 tetramethylcyclopropanecarboxylate), in or on kiwifruit, fuzzy at 5 ppm. This tolerance expires on December 31, 2022.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, titled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, titled ''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, titled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the National Government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: December 5, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.466, revise paragraph (b) to read as follows:

§ 180.466 Fenpropathrin; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in Table 2 to this paragraph (b) are established for residues of fenpropathrin, (alpha-cyano-3-phenoxy-benzyl 2,2,3,3 tetramethylcyclopropane carboxylate) in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerance expires on the date specified in Table 2.

TABLE 2 TO PARAGRAPH (b)

Commodity	Parts per million	Expiration date
Kiwifruit, fuzzy ...	5	12/31/2022

* * * * *

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