EPA-APPROVED KENTUCKY NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanations
* *	* *	*	*	*
2015 8-hour Ozone Maintenance Plan for the Kentucky Portion of the Cincinnati, OH-KY Area.	Portions of Boone, Campbell, and Kenton Counties.	9/21/2022	10/4/2023, [Insert citation of publication].	

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

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

■ 4. In § 81.318, amend the table entitled ''Kentucky—2015 8-Hour Ozone NAAQS'' by revising the entry for ''Cincinnati, OH-KY,'' to read as follows:

§ 81.318 Kentucky.

* * * * *

KENTUCKY—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Cincinnati, OH-KY	November 8, 2023	Attainment.		
Boone County (part):				
The entire county except for 2010 U.S. Census Tracts 706.01 and 706.04.				
Campbell County (part):				
The entire county except for 2010 U.S. Census Tracts 520.01 and 520.02.				
Kenton County (part):				
The entire county except for 2010 US Census Tracts 637.01 and 637.02.				
* * *	*	*	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.

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[FR Doc. 2023–21866 Filed 10–3–23; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0508 and EPA–HQ–OPP–2022–0672; FRL–11407–01–OCSPP]

Cypermethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cypermethrin in or on multiple commodities that are identified and discussed later in this document. The Tea Association of the U.S.A. Inc. and the American Spice Trade Association requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 4, 2023. Objections and requests for hearings must be received on or before December 4, 2023 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–2022–0508 and EPA–HQ–OPP–2022–0672, 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 and the OPP docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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–2022–0508 and EPA–HQ–OPP–2022–0672 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 December 4, 2023. 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–2022–0508 and EPA–HQ–OPP–2022–0672, 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.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 20, 2022 (87 FR 43231) (FRL–9410–03–OCSPP) 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 2E8990) by the Tea Association of the U.S.A. Inc., 362 5th Avenue, Suite 1002, New York, NY 10001. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide cypermethrin, including its metabolites and degradates, in or on the raw agricultural commodity tea, dried at 15 parts per million (ppm). That document referenced a summary of the petition prepared by the Tea Association of the U.S.A. Inc., the petitioner, which is available in the docket, *https://www.regulations.gov.*

In the **Federal Register** of September 23, 2022 (87 FR 58047) (FRL–9410–05–OCSPP), 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 2E9011) by the American Spice Trade Association, 1101 17th Street NW, Suite 700, Washington, DC 20036. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide cypermethrin, including its metabolites and degradates, in or on some raw agricultural spice commodities (Allspice; anise pepper; Ashwagandha fruit; Batavia-cassia, fruit; Belleric myrobalan; caper buds; cardamom, black; cardamom, Ethiopian; cardamom, green; cardamom, Nepal; cardamom-amomum; cassia, fruit; cassia, Chinese, fruit; Chinese hawthorn; Chinese-pepper; cinnamon, fruit; cinnamon, Saigon, fruit; coriander, fruit; cumin, black; Dorrigo pepper, berry; Dorrigo pepper, leaf; eucalyptus; gamboge; grains of Selim; juniper, berry; miracle fruit; pepper, black; pepper, Indian long; pepper, Javanese long; pepper, pink; pepper, Sichuan; pepper, white; pepperbush, berry; pepperbush, leaf; peppercorn, green; peppertree; peppertree, Peruvian; saunders, red; sumac, fragrant; sumac, smooth, leaf; tamarind, seed; Tasmanian, pepper, berry; Tsaoko; Vanilla), at 0.5 ppm; and on other spice commodities (angelica, seed; Asafoetida; calamus-root; chaste tree, Chinese, roots; coptis; coriander, seed; fingerroot; jalap; lovage, root; lovage, seed; yellow gentian, roots) at 0.2 ppm. That document referenced a summary of the petition prepared by the American Spice Trade Association, the petitioner, which is available in the docket, *https://www.regulations.gov.*

No comments were received on either notice of filing.

Based upon review of the data supporting the petition, EPA is revising the tolerance definition and the tolerance level for tea. The reason for these changes is 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 cypermethrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cypermethrin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The cypermethrins (cypermethrin, zeta-cypermethrin, and alpha-cypermethrin) are Type II pyrethroids that contain an alpha-cyano moiety. The

adverse outcome pathway (AOP) shared by pyrethroids involves the ability to interact with voltage-gated sodium channels (VGSCs) in the central and peripheral nervous systems leading to changes in neuron firing and, ultimately, neurotoxicity.

While each active ingredient does not have its own complete database, studies have been bridged across the three isomeric mixtures and together are considered adequate for human health risk assessment. When evaluated together, the toxicity database for cypermethrin, zeta-cypermethrin, and alpha-cypermethrin can be used to characterize the overall suite of effects associated with cypermethrin exposure, including potential developmental and reproductive toxicity, immunotoxicity, and neurotoxicity. Therefore, the toxicology database for the cypermethrins together is considered complete with respect to guideline toxicity studies.

The cypermethrins affect the nervous system, and neurotoxicity is the most sensitive effect observed throughout the toxicology database. Clinical signs of neurotoxicity were seen for all three compounds across species, sexes, and routes of administration. The endpoints and points of departure (PODs) selected for risk assessment are based on neurotoxicity and are protective of all adverse toxic effects observed in the database. EPA determined that the acute toxicity of alpha-cypermethrin is higher than that of cypermethrin and zeta-cypermethrin. To account for this toxicity difference, EPA applied a 5X toxicity factor for alpha-cypermethrin. As the current tolerance petitions are for cypermethrin, the toxicity PODs for cypermethrin were used for risk assessment.

There was no evidence of increased quantitative or qualitative susceptibility in the available rat and rabbit developmental toxicity studies and rat 2-generation reproductive studies with the cypermethrins. A developmental neurotoxicity (DNT) study with zeta-cypermethrin indicated increased sensitivity in the offspring, based on body weight changes in pups in the absence of treatment-related effects in maternal animals at the highest dose tested. However, there is a clear no-observed-adverse-effect-level (NOAEL) for effects seen in pups, and the doses and endpoints selected for risk assessment are protective of the susceptibility.

For pyrethroid chemicals, the pharmacokinetics indicate that the onset of neurotoxicity is rapid, with the time to peak effect for neurobehavioral effects occurring within hours. This is followed by rapid metabolism and elimination that does not result in bioaccumulation. For the cypermethrins, the PODs for clinical signs after single or repeated exposure are comparable across durations of exposure; thus, neurotoxicity does not seem to progress with increased exposure. Therefore, repeated dosing is essentially a series of acute exposures. As there is no apparent increase in hazard from repeated/chronic exposures to cypermethrins, the acute exposure assessment is protective of chronic exposures. The totality of the information suggests that only single day risk assessments need to be conducted for the cypermethrins.

Cypermethrin is classified as a Group C ''Possible human carcinogen,'' based on an increased incidence of benign lung adenomas and adenomas plus carcinomas combined in females in a mouse carcinogenicity study. No tumors were seen in cypermethrin cancer studies in rats or in a cancer study in mice with alpha-cypermethrin. The Agency has determined that quantification of cancer risk using a non-linear approach (*i.e.,* reference dose or RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to the cypermethrins.

Specific information on the studies received and the nature of the adverse effects caused by cypermethrin as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *https://www.regulations.gov* in document ''Cypermethrin, Human Health Risk Assessment for Proposed Tolerances on Tea and Commodities of the Codex Crop Subgroups: Spices, Fruit or Berry and Spices, Root or Rhizome. The Tolerances are Proposed Without a U.S. Registration.'' hereinafter ''Cypermethrin Human Health Risk Assessment'' at pages 32–39 in docket ID numbers EPA–HQ–OPP–2022–0508 and EPA–HQ–OPP–2022–0672.

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for cypermethrin used for human risk assessment can be found in the Cypermethrin Human Health Risk Assessment on pages 18–21.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cypermethrin, EPA considered exposure under the petitioned-for tolerances as well as all existing tolerances for the cypermethrins in 40 CFR 180.418. EPA assessed dietary exposures from cypermethrin 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 cypermethrin.

In conducting the acute dietary exposure assessment, EPA used the 2005–2010 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute dietary exposure assessment is a conservative assessment that assumes tolerance level residues for most commodities and 100 percent crop treated (PCT) for all commodities. The highest field trial values obtained in residue studies were used for the commodities that make the most significant contribution to dietary risk, specifically apples, peaches, pears, and grapes. Empirical and conservative default processing factors were used in the assessment. EPA determined that the toxicity of alpha-cypermethrin is higher than that of cypermethrin and zeta-cypermethrin. To account for this

toxicity difference, HED applied a 5X toxicity factor for alpha-cypermethrin.

ii. *Chronic exposure.* A chronic dietary risk assessment is not required for the cypermethrins 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, HED performed a chronic dietary exposure assessment in support of the current aggregate human health risk assessment. There are residential exposures for the cypermethrins that were aggregated with background exposure from dietary sources. The chronic assessment is only being used to estimate background dietary exposure to all cypermethrins.

The chronic dietary exposure assessment is a refined assessment based on Pesticide Data Program (PDP) monitoring data for most commodities. Tolerance level residues were used for a limited number of commodities including tea and spices. As with the acute assessment, empirical and conservative default processing factors were used for the processed commodities for which they were available. EPA made the conservative assumption that 100% of all commodities would be treated. When monitoring data were used, average residues were calculated by incorporating one-half limit of detection (LOD) values for all non-detects. No zeros were used to calculate the average residues. EPA accounted for the 5X toxicity difference by multiplying the average PDP values for commodities with alpha-cypermethrin tolerances by a factor of 5.

The cypermethrins have food handling establishment (FHE) uses that need to be accounted for in the chronic dietary exposure assessment. For chronic dietary assessment, EPA used a residue value of one-half the FHE tolerance. EPA estimated the probability that a food item a person consumes contains residues as a result of treatment in an FHE at some point with any pesticide. This risk assessment paradigm is generic for all pesticides. To date, such modelling is not specific to cypermethrin. This estimate is 4.65%. In the chronic assessment, this value was used for the same commodities as the ones with the FHE residue value (0.025 ppm). For all commodities with tolerances, the total anticipated residue from the agricultural use exceeded the total anticipated residue from the FHE use. For this reason, the FHE residue value was only used for commodities that don't have tolerances associated with direct application to crops.

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. Cypermethrin is classified as a ''possible human carcinogen.'' The Agency has determined that quantification of risk using a non-linear approach (*i.e.,* aPAD or aRfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to the cypermethrins.

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 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.

EPA assumed 100% crop treated for all commodities in the acute and chronic dietary exposure assessments. However, as discussed above, in the chronic assessment, a percent FHE treatment value of 4.65% was incorporated for commodities for which the FHE residue value was used.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for cypermethrin in drinking water. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment.*

In both the acute and chronic assessments, EPA used estimated drinking water concentrations (EDWCs) generated with the Surface Water Concentration Calculator (SWCC), and in both assessments, the EDWC was used for both direct and indirect water. For the acute dietary risk assessment, EPA used an (EDWC) of 3.5 ppb, and for the chronic exposure assessment (used to determine background exposure from food and drinking water for the purpose of aggregate risk assessment), EPA used an EDWC 0.035 ppb. EPA also determined groundwater EDWCs with a different model; however, the Agency used the surface water EDWCs in the assessments because the surface water EDWCs were higher than the groundwater EDWCs. The use of the surface water values in the dietary exposure assessment is protective of potential exposure through groundwater sources of 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). The cypermethrins are registered for a variety of non-agricultural purposes including recreational sites (*i.e.,* golf courses, athletic fields); indoor residential/commercial/industrial sites/structural/perimeter and lawn uses; gardens and trees; as well as mosquito adulticide, termiticide, and pet uses. The current action is for tolerances without a U.S. registration for tea and spices, so no residential handler or post-application exposures are anticipated.

For assessing aggregate exposure to adults, the Agency used exposures from the inhalation handler scenario from applying cypermethrin with a sprinkler can to home gardens. For assessing aggregate exposure to children, the Agency used exposures to children 1 to <2 years old (dermal and incidental oral) from post-application exposure to pets treated with the pet medallion/tag formulated with zeta-cypermethrin.

The PODs for the oral and dermal routes are based on the same effects: therefore, for children, the oral and dermal routes can be combined. Since the levels of concern for incidental oral risk and inhalation risk are different (100 and 30, respectively), the aggregate risk index (ARI) approach was used to calculate aggregate exposure and risk for adults. An ARI ≥1 is not of concern.

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 has determined that the pyrethroids and pyrethrins share a

common mechanism of toxicity (*https://www.regulations.gov;* EPA–HQ–OPP–2008–0489–0006). As explained in that document, the members of this group share the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. In 2011, after establishing a common mechanism grouping for the pyrethroids and pyrethrins, the Agency conducted a cumulative risk assessment (CRA) which is available at *https://www.regulations.gov;* EPA–HQ–OPP–2011–0746. In that document, the Agency concluded that cumulative exposures to pyrethroids (based on pesticidal uses registered at the time the assessment was conducted) did not present risks of concern. For information regarding EPA's efforts to evaluate the risk of exposure to this class of chemicals, refer to *https://www.epa.gov/ingredients-used-pesticide-products/registration-review-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 those uses being granted. A new turf use for the pyrethroid, tau-fluvalinate, was assessed after completion of the cumulative. The new use did impact the worst-case non-dietary risk estimates identified in the 2011 CRA for the turf scenario. However, the overall risk finding (*i.e.,* pyrethroid cumulative risk is above the Agency's level of concern (LOC) and therefore not of concern) did not change upon registration of this new use.

For the requested tolerances for tea and spices, the Agency has conducted an additional screen, taking into account all previously approved uses and these proposed tolerances. The petitioned-for tolerances 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; furthermore, the petitioned-for tolerances are not associated with any increase in residential or non-occupational exposure. 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 Food Quality Protection Act (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 quantitative or qualitative susceptibility in the available rat and rabbit developmental toxicity studies and rat 2-generation reproductive studies with the cypermethrins. A developmental neurotoxicity (DNT) study with zeta-cypermethrin indicated increased sensitivity in the offspring, based on body weight changes in pups in the absence of treatment-related effects in maternal animals at the highest dose tested. However, there is a clear NOAEL for effects seen in pups, and the doses and endpoints selected for risk assessment are protective of the susceptibility.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced from 10X to 1X. That decision is based on the following findings:

i. The toxicity database for the cypermethrins is considered complete. When evaluated together, the toxicity database for cypermethrin, zeta-cypermethrin, and alpha-cypermethrin can be used to characterize the overall suite of effects associated with cypermethrin exposure, 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 neurotoxicity) in rats, and immunotoxicity studies in rats are available.

ii. Like other pyrethroids, the cypermethrins cause neurotoxicity by interacting with sodium channels, leading to clinical signs of neurotoxicity. These effects are well characterized and adequately assessed by the available guideline and non-guideline studies. There are no residual uncertainties with regard to evidence of neurotoxicity for the cypermethrins.

iii. No evidence of increased qualitative or quantitative susceptibility was noted in the developmental toxicity or reproduction studies for the cypermethrins. However, quantitative susceptibility was seen in the rat DNT study with zeta-cypermethrin with an increased sensitivity in the offspring based on body weight changes in pups in the absence of adverse, treatment-related effects in maternal animals. The results from the DNT study are very similar to results observed in the reproduction studies where body weight changes (decreased body weight gain) were seen in maternal and offspring animals at doses similar to those in the DNT study, with no indication of increased susceptibility. Therefore, there is no residual concern for effects observed in the study since a clear developmental NOAEL and LOAEL were identified for which the selected PODs for risk assessment are protective.

iv. There are no residual uncertainties with regard to exposure. The dietary exposure assessments account for parent and metabolites of concern. In addition, they are refined, but could be more highly refined. The assessments include 100 percent crop treated assumptions, tolerance level residues for most commodities in the acute dietary exposure assessment, and default processing factors for many of the processed commodities. Furthermore, conservative, upper-bound assumptions were used to determine exposure through drinking water and residential sources, such that these exposures have not been underestimated.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to cypermethrin from food and water will utilize 71% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Acute aggregate risk estimates are not of concern for the general U.S. population or any population subgroup.

2. *Chronic risk.* A chronic dietary risk assessment is not required for cypermethrin because repeated

exposure does not result in a POD lower than that resulting from acute exposure. Therefore, the acute dietary risk assessment is protective of chronic dietary risk.

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). Cypermethrin is 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 cypermethrin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 130 for children and an ARI of 4.5 for adults. Because EPA's level of concern for cypermethrin is an MOE below 100, or an ARI below 1, these MOEs/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). While there is potential intermediate-term residential exposure, because the single dose and repeat dosing cypermethrin studies show that repeat exposures do not result in lower points of departure, the residential assessments are conducted as a series of acute exposures and the same endpoint is used regardless of duration. Therefore, the short-term aggregate assessment is considered protective of any intermediate-term exposures.

5. *Aggregate cancer risk for U.S. population.* EPA has classified cypermethrin as a ''possible human carcinogen'' and determined that a non-linear approach relying on the acute regulatory endpoints should be used for cancer assessment. As the acute dietary exposure estimates are not of concern, cancer risk is not of concern.

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 cypermethrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate tolerance-enforcement methods are available in PAM (Pesticide Analytical Manual) Volume II for determining residues of zeta-cypermethrin in plant (Method I) and livestock (Method II) commodities. Both methods are gas chromatographic methods with electron-capture detection (GC/ECD) and have undergone successful Agency petition method validations (PMVs). These methods are not stereospecific; therefore, no distinction is made between residues of cypermethrin (all 8 stereoisomers), zeta-cypermethrin (enriched in 4 isomers) and alpha-cypermethrin (enriched in 2 isomers).

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).

Codex has established an MRL of 15 ppm for residues of cypermethrin in or on tea. The U.S. tolerance for residues of cypermethrin in or on Tea, dried is harmonized with the Codex MRL.

Codex has established an MRL of 0.5 ppm for residues of cypermethrin on the crop subgroup Spices, Fruits and Berries and an MRL of 0.2 ppm for residues on the crop subgroup Spices, Roots and Rhizomes. The U.S. tolerances for residues of cypermethrin in or on the individual spice commodities are harmonized with the relevant Codex MRL.

C. Revisions to Petitioned-For Tolerances

The Tea Association requested a tolerance of 15.0 ppm for Tea. The United States conforms to OECD rounding classes when setting tolerances and is establishing the tolerance level at 15 ppm rather than 15.0 ppm for Tea, dried.

V. Conclusion

Therefore, tolerances are established for residues of cypermethrin, including its metabolites and degradates, in or on Allspice at 0.5 ppm; Angelica, seed at 0.2 ppm; Anise pepper at 0.5 ppm; Asafoetida at 0.2 ppm; Ashwagandha fruit at 0.5 ppm; Batavia-cassia, fruit at 0.5 ppm; Belleric myrobalan at 0.5 ppm; Calamus-root at 0.2 ppm; Caper buds at 0.5 ppm; Cardamom, black at 0.5 ppm; Cardamom, Ethiopian at 0.5 ppm; Cardamom, green at 0.5 ppm; Cardamom, Nepal at 0.5 ppm; Cardamom-amomum at 0.5 ppm; Cassia, fruit at 0.5 ppm; Cassia, Chinese, fruit at 0.5 ppm; Chaste tree, Chinese, roots at 0.2 ppm; Chinese hawthorne at 0.5 ppm; Chinese-pepper at 0.5 ppm; Cinnamon, fruit at 0.5 ppm; Cinnamon, Saigon, fruit at 0.5 ppm; Coptis at 0.2 ppm; Coriander, fruit at 0.5 ppm; Coriander, seed at 0.2 ppm; Cumin, black at 0.5 ppm; Dorrigo pepper, berry at 0.5 ppm; Dorrigo pepper, leaf at 0.5 ppm; Eucalyptus at 0.5 ppm; Fingerroot at 0.2 ppm; Gamboge at 0.5 ppm; Grains of Selim at 0.5 ppm; Jalap at 0.2 ppm; Juniper, berry at 0.5 ppm; Lovage, root at 0.2 ppm; Lovage, seed at 0.2 ppm; Miracle fruit at 0.5 ppm; Pepper, black at 0.5 ppm; Pepper, Indian long at 0.5 ppm; Pepper, Javanese, long at 0.5 ppm; Pepper, pink at 0.5 ppm; Pepper, Sichuan at 0.5 ppm; Pepper, white at 0.5 ppm; Pepperbush, berry at 0.5 ppm; Pepperbush, leaf at 0.5 ppm; Peppercorn, green at 0.5 ppm; Peppertree at 0.5 ppm; Peppertree, Peruvian at 0.5 ppm; Saunders, red at 0.5 ppm; Sumac, fragrant at 0.5 ppm; Sumac, smooth, leaf at 0.5 ppm; Tamarind, seed at 0.5 ppm; Tasmanian, pepper, berry at 0.5 ppm; Tea, dried at 15 ppm; Tsaoko at 0.5 ppm; Vanilla at 0.5 ppm; and Yellow gentian, roots at 0.2 ppm.

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). 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: September 24, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

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

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

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

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

■ 2. In § 180.418, revise paragraph (a)(1) to read as follows:

§ 180.418 Cypermethrin and isomers alpha-cypermethrin and zeta-cypermethrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide cypermethrin (±)alpha cyano-(3-phenoxyphenyl)methyl (±)cis,trans-3(2,2-dichloroethenyl-2,2-dimethylcyclopropanecarboxylate in or on the commodities in table 1 to paragraph (a)(1).

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Allspice [1]	0.5
Angelica, seed [1]	0.2
Anise pepper [1]	0.5
Asafoetida [1]	0.2
Ashwagandha fruit [1]	0.5
Batavia-cassia, fruit [1]	0.5
Belleric myrobalan [1]	0.5
Brassica, head and stem, subgroup 5A	2.0
Brassica, leafy greens, subgroup 5B	14.0
Calamus-root [1]	0.2
Caper buds [1]	0.5
Cardamom, black [1]	0.5
Cardamom, Ethiopian [1]	0.5
Cardamom, green [1]	0.5
Cardamom, Nepal [1]	0.5
Cardamom-amomum [1]	0.5
Cassia, fruit [1]	0.5
Cassia, Chinese, fruit [1]	0.5
Cattle, fat	1.0
Cattle, meat	0.2
Cattle, meat byproducts	0.05
Chaste tree, Chinese, roots [1]	0.2
Chinese hawthorne [1]	0.5
Chinese-pepper [1]	0.5
Cinnamon, fruit [1]	0.5
Cinnamon, Saigon, fruit [1]	0.5
Coptis [1]	0.2
Coriander, fruit [1]	0.5
Coriander, seed [1]	0.2
Cotton, gin byproducts	11.0
Cotton, undelinted seed	0.5
Cumin, black [1]	0.5
Dorrigo pepper, berry [1]	0.5
Dorrigo pepper, leaf [1]	0.5
Egg	0.05
Eucalyptus [1]	0.5
Fingerroot [1]	0.2
Gamboge [1]	0.5
Grains of Selim [1]	0.5
Goat, fat	1.0
Goat, meat	0.2
Goat, meat byproducts	0.05
Hog, fat	0.1
Hog, meat	0.05
Horse, fat	1.0
Horse, meat	0.2
Horse, meat byproducts	0.05
Jalap [1]	0.2
Juniper, berry [1]	0.5
Lettuce, head	4.0
Lovage, root [1]	0.2
Lovage, seed [1]	0.2
Milk, fat (reflecting 0.10 in whole milk)	2.5
Miracle fruit [1]	0.5
Onion, bulb	0.1
Onion, green	6.0
Pecan	0.05
Pepper, black [1]	0.5
Pepper, Indian long [1]	0.5
Pepper, Javanese, long [1]	0.5
Pepper, pink [1]	0.5
Pepper, Sichuan [1]	0.5
Pepper, white [1]	0.5
Pepperbush, berry [1]	0.5
Pepperbush, leaf [1]	0.5
Peppercorn, green [1]	0.5
Peppertree [1]	0.5
Peppertree, Peruvian [1]	0.5
Poultry, fat	0.05
Poultry, meat	0.05
Saunders, red [1]	0.5
Sheep, fat	1.0
Sheep, meat	0.2
Sheep, meat byproducts	0.05
Sumac, fragrant [1]	0.5
Sumac, smooth, leaf [1]	0.5
Tamarind, seed [1]	0.5
Tasmanian, pepper, berry [1]	0.5
Tea, dried [1]	15
Tsaoko [1]	0.5
Vanilla [1]	0.5
Yellow gentian, roots [1]	0.2

[1] There are no U.S. registrations as of October 4, 2023.

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