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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0220; FRL-12817-01-OCSPP]

Cypermethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance action for residues of cypermethrin (CASRN 52315-07-8) in or on the food and feed commodities of durian. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the United States Department of Agriculture (USDA) submitted a petition to EPA requesting that EPA establish a maximum permissible level for residues of this pesticide on in or on the identified commodity(ies).

DATES: This rule is effective on [**INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER***]. Objections and requests for hearings must be received on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2024-0220, is available at *https://www.regulations.gov.* Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *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. Executive Summary

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 might apply to them:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. *What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(b)(2)(A)(i) 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." FFDCA section 408(b)(2)(A)(ii) 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. FFDCA section 408(b)(2)(C) 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. . ."

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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-2024-0220 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 [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***].

EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. *See* "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at *https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf*. Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf*.

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. 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. If you wish to include CBI in your

request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned-For Tolerance

In the ***Federal Register*** of August 8, 2024 (89 FR 64842 (FRL-11682-06-OSCPP)), 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 4E9129) by the United States Department of Agriculture (USDA), 1400 Independence Avenue SW, Washington, DC 20250-1032. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide cypermethrin in or on durian at 1.0 parts per million (ppm). That document referenced a summary of the petition that was prepared by the petitioner and included in the docket.

There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is revising the tolerance definition for cypermethrin and setting a tolerance level for durian.

III. Final Tolerance Action

A. *Aggregate Risk Assessment and Determination of Safety*

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein**,** 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.

B. *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.

Cypermethrin is a mixture of eight different isomers, all of which are present in equal amounts. Alpha-cypermethrin and zeta-cypermethrin are separate mixtures of the same isomers; however, they are enriched in the most insecticidally active isomers. All three have the same toxicological mode of action and are collectively grouped together as "the cypermethrins" for assessment purposes.

The cypermethrins are Type II pyrethroids that contain an alpha-cyano moiety. The adverse outcome pathway shared by pyrethroids involves the ability to interact with voltage-gated sodium channels in the central and peripheral nervous systems leading to changes in neuron firing and, ultimately, neurotoxicity.

The toxicology database for the cypermethrins 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 effects observed in the database.

The Health Effects Division (HED) determined that the acute 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 to commodities that have established tolerances 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 two-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 the 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" under the 1986 Agency Cancer Guidelines, based on an increased incidence of benign lung adenomas and adenomas plus carcinomas combined in females in a mouse carcinogenicity study (J. Quest, TXR# 0055252, Peer Review of Cypermethrin. February 17, 1988; Guidelines for Carcinogen Risk Assessment, 51 FR 33992, September 24, 1986). 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 (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 a Proposed Tolerance Without a U.S. Registration on Durian," hereinafter "Cypermethrin Human Health Risk Assessment" at pages

32-39 in docket ID number EPA-HQ-OPP-2024-0220.

C. *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.

D. *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 the cypermethrins in food as follows:

a. *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), https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweianhanes-overview/. 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 multiplied average monitoring data values by a factor of 5.

b. *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. In the aggregate human health risk assessment, the chronic exposure estimates are combined with the appropriate residential exposure estimates and compared to the POD for cypermethrin.

The chronic dietary exposure assessment is a highly refined assessment based on Pesticide Data Program monitoring data for most commodities. To account for the 5x toxicity difference for alpha-cypermethrin, HED multiplied average monitoring data values by a factor of

5. Tolerance level residues were used for a small number of commodities. As with the acute assessment, empirical and conservative default processing factors were used for the processed commodities for which they were available. HED made the conservative assumption that 100% of all commodities would be treated. As a result, when monitoring data were used, average residues were calculated by incorporating ½ limit of detection values for all non-detects. No zeros were used to calculate the average residues.

The cypermethrins have food handling establishment (FHE) uses that need to be accounted for in the chronic dietary exposure assessment. For these uses, HED used a residue value of one-half the FHE tolerance multiplied by a factor of 5. OPP's Biological and Economic Analysis Division (BEAD) provided an estimate of 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 (J. Becker, Upper Bound Estimate of the Likelihood of Pesticide Residues on Food Resulting from Treatment in Food Handling Establishments, BEAD, 10/7/2014). It is not specific to the cypermethrins. 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 (0.125 ppm).

c. *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.

d. *Anticipated residue and percent crop treated (PCT) information*. FFDCA section 408(b)(2)(E) 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 in Unit D.1.i.b., in the chronic assessment, a percent FHE treatment value of 4.65% was incorporated for commodities for which the FHE residue value was used. EPA estimates the percent of commodities treated in FHEs for uses of active ingredients based on the best available information. This includes survey information on pesticide usage related to the number of facilities being treated, product forms used (e.g., liquids and aerosols), and treatment schedule by FHE segments (e.g., warehouse, food processor, distributor, and restaurant). EPA also incorporated the best available information related to the transfer of commodities between various segments of FHEs and the percent of food consumed by location, either in the home or outside the home.

All information currently available has been considered and EPA has concluded that for any active ingredient, including cypermethrin, there is at most a 4.65% likelihood that a food commodity could contain potential residues resulting from one or more treatments while in the FHE channel of trade. EPA intends to periodically re-evaluate this conclusion consistent with its obligations in the FFDCA

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 *https://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, and in

both assessments, the EDWC was used for both direct and indirect water. Also, in both assessments, the EDWCs were adjusted by toxicity and application rate factors. For the acute dietary risk assessment, EPA used a value of 4.375 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 a value of 0.044 ppb. EPA also determined groundwater EDWCs with a different model; however, the Agency used the adjusted 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. *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 corresponding U.S. registration for use on durian, so no new 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 $\geq$ 1 is not

of concern. The aggregate risk estimates are not of concern, as the ARIs are greater than 1.0.

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*. FFDCA section 408(b)(2)(D)(v) 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 pyrethrins, which are Type II pyrethroids, thus share a common mechanism of toxicity with other pyrethroids (*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) (*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 2011 CRA. 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 and therefore not of concern) did not change upon evaluation of this new cypermethrin tolerance for durian.

The recommended tolerance for durian will not significantly impact the 2011 CRA because durian makes an insignificant contribution to dietary exposure, and dietary exposures make a minor contribution to total pyrethroid exposure relative to residential exposures in the 2011 CRA; furthermore, the proposed tolerance is 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.

E. *Safety Factor for Infants and Children*

1. *In general*. FFDCA section 408(b)(2)(C) 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 two-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:

• 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.

• 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.

• 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.

• 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.

F. *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 the 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.* 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 the cypermethrins 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 140 for children and an ARI of 4.6 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, 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 residues of the cypermethrins.

IV. Other Considerations

A. *Analytical enforcement methodology.*

Adequate enforcement methodology as described in the supporting document is available to enforce the tolerance expression. Adequate data have been submitted to support the proposed tolerance for residues in or on durian. There are no outstanding data with respect to tolerances. The tolerance expression for cypermethrin in 40 CFR 180.418(a)(1) needs to be updated to include the coverage and compliance statements. The statement should be revised to read as follows: "Tolerances are established for residues of cypermethrin, (±)alpha cyano-(3-phenoxyphenyl)methyl (±)cis,trans-3(2,2-dichloroethenyl-2,2-dimethylcyclopropanecarboxylate, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only total cypermethrin, cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-

dimethylcyclopropane carboxylate, in or on the commodity." The tolerance expressions for alpha-cypermethrin and zeta-cypermethrin are currently up to date and need no revisions.

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.

Codex has established an MRL of 1 ppm for residues of cypermethrin in or on durian. The U.S. tolerance for residues of cypermethrin in or on durian is harmonized with the Codex MRL.

C. *Revisions to petitioned-for tolerances.*

USDA requested a tolerance of 1.0 ppm for durian. The United States conforms to the Organisation for Economic Co-operation and Development rounding classes when setting tolerances and is establishing the tolerance level at 1 ppm rather than 1.0 ppm for durian.

V. Conclusion

Therefore, tolerances are established for residues of cypermethrin, including its metabolites and degradates, in or on durian at 1 ppm. EPA is also revising the tolerance expression to clarify that (1) as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of cypermethrin not specifically mentioned; and (2) compliance with the specified tolerance levels is to be determined by measuring only the specific compounds

mentioned in the tolerance expression. 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

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. *Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

B. *Executive Order 14192: Unleashing Prosperity Through Deregulation*

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork *Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq*., because it does not contain any information collection activities.

D. *Regulatory Flexibility Act (RFA)*

Since tolerance actions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the RFA, 5 U.S.C. 601 *et seq*., do not apply to this action.

E. *Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more (in 1995

dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or on the private sector.

F. *Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. *Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because tolerance actions like this one are exempt from review under Executive Order 12866. However, EPA's 2021 *Policy on Children's Health* applies to this action.

This rule finalizes tolerance actions under the FFDCA, which 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 ..." (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in the pesticide-specific registration review documents*, located* in each chemical docket at *https://www.regulations.gov*.

I. *Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy*

Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. *National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. *Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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: July 14, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons set forth 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 and republish 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 cypermethrin, (±)alpha cyano-(3-phenoxyphenyl)methyl (±)cis,trans-3(2,2-dichloroethenyl-2,2-dimethylcyclopropanecarboxylate, including its metabolites and degradates, in or on the commodities in table 1 to paragraph (a). Compliance with the tolerance levels specified in the following table is to be determined by measuring only total cypermethrin, cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate, in or on the commodity.

Table 1 to Paragraph (a)

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-casia, 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

Commodity	Parts per million
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
Durian[1]	1
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

Commodity	Parts per million
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 [**INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

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