those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(iii) Documentation showing that the veteran is an Eskimo or Aleut or other Alaska Native;

(iv) Documentation issued by the Department of Interior (DOI) showing that the veteran is considered by DOI to be an Indian for any purpose;

(v) Documentation showing that the veteran is considered by the Department of Health and Human Services (HHS) to be an Indian under that Department's regulations; or

(vi) Documentation showing that the veteran resides in an urban center and meets one or more of the following criteria:

(A) Irrespective of whether they live on or near a reservation, is a member of a Tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(B) Is an Eskimo or Aleut or other Alaska Native;

(C) Is considered by DOI to be an Indian for any purpose; or

(D) Is considered by HHS to be an Indian under that Department's regulations.

(g) *Retroactive copayment reimbursement.* After VA determines the submitted documentation meets paragraph (f)(11) of this section and updates the veteran's record to reflect the veteran's status as an Indian or urban Indian, VA will reimburse veterans exempt under paragraph (f)(11) for any copayments that were paid to VA for adult day health care, non-institutional respite care, and non-institutional geriatric evaluation provided on or after January 5, 2022, if they would have been exempt from making such copayments if paragraph (f)(11) had been in effect.

(The Office of Management and Budget has approved the information collection provisions in this section under control number 2900–TBD.)

■ 5. Amend § 17.4600 by revising paragraph (d)(1) and adding paragraph (d)(4) and the information collection control number to the end of the section to read as follows:

§ 17.4600 Urgent care.

* * * * *

(d) * * *

(1) Except as provided in paragraphs (d)(2) through (4) of this section, an eligible veteran, as a condition for receiving urgent care provided by VA under this section, must agree to pay VA (and is obligated to pay VA) a copayment of $30:

* * * * *

(4)(i) If an eligible veteran meets the definition of Indian or urban Indian, as defined in 25 U.S.C. 1603(13) and (28), they are exempt from copayments for all urgent care visits. To demonstrate that they meet the definition of Indian or urban Indian, the veteran must submit to VA any of the documentation described in paragraphs (d)(4)(i)(A) through (F) of this section:

(A) Documentation issued by a federally recognized Indian Tribe that shows that the veteran is a member of the Tribe;

(B) Documentation showing that the veteran, irrespective of whether they live on or near a reservation, is a member of a Tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(C) Documentation showing that the veteran is an Eskimo or Aleut or other Alaska Native;

(D) Documentation issued by the Department of Interior (DOI) showing that the veteran is considered by DOI to be an Indian for any purpose;

(E) Documentation showing that the veteran is considered by the Department of Health and Human Services (HHS) to be an Indian under that Department's regulations; or

(F) Documentation showing that the veteran resides in an urban center and meets one or more of the following criteria:

(*1*) Irrespective of whether they live on or near a reservation, is a member of a Tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(*2*) Is an Eskimo or Aleut or other Alaska Native;

(*3*) Is considered by DOI to be an Indian for any purpose; or

(*4*) Is considered by HHS to be an Indian under that Department's regulations.

(ii) After VA determines the submitted documentation meets paragraph (d)(4)(i) of this section and updates the veteran's record to reflect the veteran's status as an Indian or urban Indian, VA will reimburse eligible veterans exempt under paragraph (d)(4)(i) for any copayments that were paid to VA for urgent care visits provided on or after January 5, 2022, if they would have been exempt from making such copayments if paragraph (d)(4)(i) had been in effect.

* * * * *

(The Office of Management and Budget has approved the information collection provisions in this section under control number 2900–TBD.)

[FR Doc. 2023–06954 Filed 4–3–23; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0671; FRL–10568–01–OCSPP]

Deltamethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of deltamethrin in or on the raw agricultural commodities, Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E and Vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 4, 2023. Objections and requests for hearings must be received on or before June 5, 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–2022–0671, 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: Daniel Rosenblatt, Acting 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–2022–0671 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 June 5, 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–2022–0671, 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/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/.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 30, 2022 (87 FR 52868) (FRL–9410–04–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 1E8933) by Bayer CropScience, 800 N Lindbergh Blvd., St. Louis, MO 63141. The petition requested that 40 CFR 180.435 be amended by establishing tolerances without U.S. Registration for residues of deltamethrin, (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-, in or on the raw agricultural commodity, Crop Subgroup 6C (Pea and bean, dried, shelled, except soybean) at 0.07 parts per million (ppm). That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing tolerances for two subgroups in the recently revised Legume vegetable crop group 6–22 instead of Crop Subgroup 6C (Pea and bean, dried, shelled, except soybean) as requested by the petitioner.

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 deltamethrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with deltamethrin 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 toxicology database for deltamethrin is complete except for the subchronic inhalation study which the Hazard Science and Policy Council (HASPOC) recommended to require (TXR 0058335, Z. Staley, 09/30/2022).

Deltamethrin is a member of the pyrethroid class of insecticides. Pyrethroids have historically been classified into two groups, Type I and Type II, based on chemical structure and toxicological effects. Deltamethrin is a Type II pyrethroid. Type II pyrethroids, which contain an alpha-cyano moiety, produce a syndrome in rats that includes pawing, burrowing,

salivation, hypothermia, and coarse tremors leading to choreoathetosis (CS-syndrome). The adverse outcome pathway (AOP, identified using a weight-of-evidence approach based on the Bradford-Hill criteria) 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.

Deltamethrin has been evaluated for a variety of effects in experimental toxicity studies. Neurotoxicity was observed throughout the database, and effects were seen across species, sexes, exposure durations, and routes of administration. Clinical signs characteristic of Type II pyrethroids, such as increased salivation, altered mobility/gait, and tremors, were seen in experimental toxicology studies including neurotoxicity studies (acute and subchronic) in rats, subchronic and chronic studies in dogs and rats, and developmental and reproduction studies in rats. In addition to the clinical signs noted above, increased sensitivity to external stimuli, abnormal vocalization, and decreased fore- and hind-limb grip strength were commonly observed in the database.

Deltamethrin did not have any adverse effects on fetuses or offspring in the prenatal developmental studies in rats and rabbits, therefore there was no evidence of quantitative or qualitative susceptibility in these studies. However, qualitative susceptibility was observed at high doses in the developmental neurotoxicity (DNT) and 2-generation reproduction studies because the effects in the offspring were more severe than the maternal effects. In the DNT study, an increased incidence of vocalization when handled was observed during FOB observations on PND 4 for male pups and decreased pre- and post-weaning body weight was observed in pups of both sexes. In maternal animals, only decreased body weight and body weight gain were observed, and no adverse FOB effects were observed despite having undergone the same neurological measurements as the pups, including FOB analysis. In the 2-generation reproduction study, treatment-related effects in the parental animals at the high dose were limited to lesions on the head, neck, or forelimbs, and alopecia in the males and ataxia and hypersensitivity in the females during gestation. At the high dose in the F1 generation, there were increased pup mortalities (PND 8–14) and clinical findings observed early in the post-weaning period (*i.e.,* impaired righting reflexes, hyperactivity, splayed limbs, vocalization, and excessive salivation). There was no increase in mortality or clinical signs in the F2 generation. Decreased body weight was observed in the adult P and F1 generations, and decreased pup weight was observed in both the F1 and F2 pups.

In a 21-day dermal toxicity study, no systemic toxicity was observed up to the limit dose. There was also no toxicity observed following acute dermal exposure to deltamethrin up to a dose of 2,000 mg/kg/day. The dermal absorption value for deltamethrin is 11.3%.

There was no evidence of immunotoxicity in the available studies with deltamethrin.

There was no evidence of carcinogenicity in the combined chronic/carcinogenicity study in rats or the carcinogenicity study in mice. In a battery of mutagenicity studies, there was no evidence of a mutagenic effect.

Specific information on the studies received and the nature of the adverse effects caused by deltamethrin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *https://www.regulations.gov* in document ''Deltamethrin Human Health Risk Assessment for the Proposed Tolerances on Vegetable, Legume, Pulse, Bean, Dried Shelled, Except Soybean, Subgroup 6–22E and Vegetable, Legume, Pulse, Pea, Dried Shelled, Subgroup 6–22F, without U.S. Registration'' (hereinafter ''Deltamethrin Human Health Risk Assessment'') at 29–34 in docket ID number EPA–HQ–OPP–2022–0671.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (PODs) 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 deltamethrin used for human risk assessment can be found on pages 17–18 in the ''Deltamethrin Human Health Risk Assessment''.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to deltamethrin, EPA considered exposure under the petitioned-for tolerances as well as all existing deltamethrin tolerances in 40 CFR 180.435. EPA assessed dietary exposures from deltamethrin 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 deltamethrin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2005–2010 National Health and Nutrition Examination Survey, What We Eat in American (NHANES/WWEIA). As to residue levels in food, the acute dietary exposure is partially refined; the residue inputs were a combination of tolerance-level residues, Pesticide Data Program (PDP) monitoring data, and mosquito adulticide residue values. As deltamethrin is registered for use as a mosquito adulticide, residue estimates for the adulticide use were included in the dietary exposure assessment. EPA used percent crop treated (PCT) for some commodities as described below and 100 PCT for the other commodities.

ii. *Chronic exposure.* A chronic dietary risk assessment is not required for deltamethrin because repeated exposure does not result in a POD lower than that resulting from acute exposure. Therefore, the acute dietary risk assessment is protective of chronic dietary risk. However, EPA performed a chronic dietary exposure assessment for use in the aggregate assessment, since there are residential exposures for deltamethrin that need to be aggregated with background exposure from dietary

sources. In the aggregate human health risk assessment, the average or chronic exposure estimates are combined with the appropriate residential exposure estimates and compared to the POD for deltamethrin.

In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2005–2010 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, the chronic dietary exposure is partially refined; the residue inputs consisted of a combination of tolerance level residues, PDP monitoring data, mosquito adulticide residue values, and Food Handling Establishment (FHE) residue values. EPA used percent crop treated (PCT) estimates for some commodities and 100 PCT for the other commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that deltamethrin is not likely to be carcinogenic 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 chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the dietary assessment, the following PCT assumptions were made:

The maximum PCT estimates used in the acute dietary risk assessment for the following crops that are currently registered for deltamethrin were: apples, 2.5%; carrots, 5%; cucumbers, 5%; soybeans, 2.5%; and watermelons, 10%. In addition, EPA used a value of 9% as an estimate of the percentage of the orange crop that might be imported. EPA assumed 100 PCT for all other commodities included in the acute assessment.

The average PCT estimates used in the chronic dietary risk assessment for the following crops that are currently registered for deltamethrin were: apples, 1%; globe artichokes, 5%; carrots, 1%; cotton, 1%; cucumbers, 1%; leeks, 1%; onions, 1%; potatoes, 1%; pumpkins, 2.5%; rapeseed, 2.5%; shallot, 1%; squash, 1%; sunflowers, 5%; and watermelons, 1%. EPA assumed 100 PCT for all other commodities included in the chronic assessment.

In the chronic assessment, for the commodities that are only covered by the FHE tolerance, the assumption was made that there was a 4.65% chance that a food item consumed by a person contained deltamethrin residues as a result of treatment at some point in an FHE.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5%, respectively. The maximum PCT figure is the highest observed maximum value reported within the recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which deltamethrin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for deltamethrin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of deltamethrin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www.epa.gov/science-and-assessing-pesticide-risks/pesticide-risk-assessment.*

The deltamethrin limit of solubility is 0.20 ppb. EPA used 0.20 ppb as the estimated drinking water concentration (EDWC) for both the acute and chronic dietary assessments because the concentration of deltamethrin in water cannot exceed the limit of solubility.

Although a chronic dietary endpoint was not identified for deltamethrin, a chronic dietary exposure assessment was performed to provide background exposure for the aggregation with short-term residual exposure.

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).

There are no proposed residential uses associated with the proposed use on imported peas and beans. However, deltamethrin is currently registered for the following uses that could result in residential exposures: Indoor (spot, crack and crevice) and outdoor (turf, garden and trees) environments, pet collars, paint preservative, impregnated mosquito net, and wide area mosquito and fly control.

In the previous risk assessment, all residential handler scenarios (adults only) resulted in inhalation risk estimates greater than the LOC (*i.e.,* MOEs ≥ 1,000), with MOEs ranging from 1,200 to 850,000, which are not of concern. No risk estimates of concern were identified for residential post-application exposure scenarios (children's incidental oral). The MOEs ranged from 290 to 1,500,000 and were greater than the LOC of 100.

Although there are no residential uses associated with the proposed tolerances, the aggregate human health risk assessment was updated to include the additional dietary exposure expected from residues in peas and beans. EPA selected only the most conservative, or worst- case, residential adult and child scenarios to be included in the aggregate estimates, based on the lowest overall MOE (*i.e.,* highest exposure and risk estimates). The adult worst-case residential handler exposure estimate resulted from adults fastening (applying) pet collars treated with deltamethrin to large dogs. The children's (1 to <2 years old) worst-case residential exposure estimate resulted from hand-to-mouth (post-application) exposure to residues from perimeter/spot treatments on carpeting.

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/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/used-pesticide-products/registration-review-pyrethrins-and-pyrethroids*.

Deltamethrin is included in the pyrethroids/pyrethrins cumulative risk assessment. No dietary, residential, or aggregate risk estimates of concern have been identified in the single chemical assessment. In the cumulative assessment, residential exposure was the greatest contributor to the total exposure. Dietary exposures make a minor contribution to the total pyrethroid exposure. The dietary exposure assessment performed in support of the pyrethroid cumulative was much more highly refined than that performed for deltamethrin. The minor increase in dietary exposure to deltamethrin residues, as a result of the proposed tolerance, would make an insignificant contribution to cumulative exposure.

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.* Deltamethrin did not have any adverse effects on fetuses or offspring in the prenatal developmental studies in rats and rabbits. However, qualitative susceptibility was observed at high doses in the developmental neurotoxicity (DNT) and 2-generation reproduction study. In the DNT study, an increased incidence of vocalization when handled was observed during FOB observations on PND 4 for male pups and decreased pre- and post-weaning body weight was observed in pups of both sexes. In maternal animals, only decreased body weight and body weight gain were observed despite undergoing the same neurological measurements as the pups, including FOB analysis. In the 2-generation reproduction study, treatment-related effects in the parental animals at the high dose were limited to lesions on the head, neck, or forelimbs, and alopecia in the males and ataxia and hypersensitivity in the females during gestation. At the high dose in the F1 generation, there were increased pup mortalities (PND 8–14) and clinical findings observed early in the post-weaning period (*i.e.,* impaired righting reflexes, hyperactivity, splayed limbs, vocalization, and excessive salivation). There was no increase in mortality or clinical signs in the F2 generation. Decreased body weight was observed in the adult P and F1 generations, and decreased pup weight was observed in both the F1 and F2 pups.

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 with the exception of inhalation exposure scenarios, for which the 10X FQPA Safety Factor was retained as a database uncertainty factor. That decision is based on the following findings:

i. The toxicity database for deltamethrin is complete, except for a subchronic inhalation study that HASPOC recommended not to waive (TXR 0058335, Z. Staley, 09/30/2022). Studies that are available to inform the FQPA SF include developmental toxicity studies in rats and rabbits, a reproduction study in rats, an acute neurotoxicity (ACN) study, a subchronic neurotoxicity (SCN) study, and developmental neurotoxicity (DNT) studies.

ii. There is evidence of neurotoxicity in the deltamethrin toxicology database. As with other pyrethroids, deltamethrin causes neurotoxicity from interaction with sodium channels leading to clinical signs of neurotoxicity. These effects are well characterized and adequately assessed by the body of data available to the Agency, therefore, there is no residual uncertainty regarding neurotoxicity.

iii. There were no indications of fetal toxicity in any of the guideline studies, including developmental studies in the

rat and rabbit, a developmental neurotoxicity study in rats, and a 2-generation reproduction study in rats. There was evidence of increased juvenile qualitative susceptibility at high doses observed in both the DNT and 2-generation reproduction studies. In the DNT study, increased vocalization was observed during FOB handling of pups on PND 4 at the same dose where decreased body weight and body weight gain were observed in maternal animals (16.1 mg/kg/day). No findings were observed in the maternal animals during FOB handling in the DNT. In the 2-generation reproduction study, the P generation showed limited clinical signs of neurotoxicity and decreased body weights at the highest dose tested (21.2/23.5 mg/kg/day, M/F). Effects observed in the F1 generation at the same dose included decreased pup weight, increased pup mortality between PND 8–14, increased pup mortality within the first 8 days post-weaning, and additional clinical signs of neurotoxicity not observed in the parental generation. The increased mortality and additional clinical signs were considered evidence of qualitative sensitivity in juveniles.

iv. *There are no residual uncertainties identified in the exposure databases.* The dietary exposure assessments are based on a combination of robust monitoring data and field trial residue levels that account for parent and metabolites of concern, processing factors, and percent crop treated assumptions. 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 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 deltamethrin will occupy 26% of the aPAD for children 3 to 5 years old, the population group receiving the greatest exposure.

Acute aggregate risk of exposure to deltamethrin results from exposure to residues in food and drinking water alone. Therefore, acute aggregate risk estimates are equivalent to the acute dietary risk estimates, which are below the level of concern of 100% of the aPAD. Acute aggregate risk estimates are not of concern for the general U.S. population or any population subgroup.

2. *Chronic risk.* Based on the data summarized in Unit III.A., there is no increase in hazard with increasing dosing duration. As a result, there is no increase in toxicity with repeated/chronic dietary exposures; therefore, the acute aggregate assessment is protective of potential chronic aggregate exposures.

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). Deltamethrin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to deltamethrin.

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 MOEs of 260 for children 1 to 2 years old. Because this MOE is greater than the LOC of 100 for dietary and children's hand-to-mouth exposure, the short-term aggregate risk estimate for children 1 to 2 years old is not of concern. The combined short-term food, water and residential exposures for adults results in an aggregate risk index (ARI) of 1.2, which is greater than EPA's level of concern of an ARI of 1, so these risks are also not of concern. EPA used an ARI approach for the adult short-term risk because the level of concern for dietary exposure (100) is different than the level of concern for inhalation exposure (1,000).

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because toxicity does not increase with repeated dosing, intermediate-term risk is covered by the assessments for short-term exposures.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, deltamethrin 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 deltamethrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with electron capture detection (GC/ECD) method) is available in PAM Volume II (Section 180.422) is available to enforce the tolerance expression. Two other GC/ECD methods are also available for enforcing deltamethrin tolerances in plant commodities.

The methods 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 established MRLs for deltamethrin in or on the raw or processed agricultural commodities, Pulses (group) at 1 ppm. The Codex MRL is much higher and is based on a post-harvest use. EPA cannot harmonize the tolerance of 0.07 ppm because of the large difference in the values which would limit its usefulness as an enforcement tool. However, EPA will be harmonizing with the Canadian MRL of 0.07 ppm for the equivalent subgroups.

C. Revisions to Petitioned-For Tolerances

FFDCA section 408(d)(4)(A)(i) permits the Agency to finalize a tolerance that varies from that sought by the petition. EPA is establishing tolerances for two subgroups in the recently revised Legume vegetable crop group 6–22 instead of Crop Subgroup 6C (Pea and bean, dried, shelled, except soybean) (See Pesticides; Expansion of Crop Grouping Program VI, (87 FR 57627) (September 21, 2022) (FRL–5031–13–OCSPP). The revised subgroups ''Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E'' and ''Vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F'' include all commodities in the original crop subgroup 6C while also aligning with the updated crop groups.

V. Conclusion

Therefore, tolerances are established for residues of deltamethrin, (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-, in or on the raw or processed agricultural commodities, Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E and Vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F at 0.07 ppm. As a housecleaning activity, EPA is removing the first footnote to the table in paragraph (a)(1) because it is unnecessary and included in the second footnote.

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 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).

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: March 29, 2023.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—TOLERANCE 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 § 180.435, amend paragraph (a)(1) by:

■ a. Adding a heading to the table;

■ b. Adding in alphabetical order to the table entries for ''Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E [1]'' and ''Vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F [1]'';

■ c. Revising the table footnotes.

The additions and revision read as follows:

§ 180.435 Deltamethrin; tolerances for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E [1]	0.07
Vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F [1]	0.07
* * * * *	

* There are no U.S. registrations.

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

* * * * *

[FR Doc. 2023–06939 Filed 4–3–23; 8:45 am]

BILLING CODE 6560–50–P