received by 5:00 p.m. Eastern time on the due date; or

(iv) They are hand-delivered by commercial courier to the Congressional Courier Acceptance Site in accordance with § 301.2(c) of this chapter and received by 4:00 p.m. Eastern time on the due date.

(6) Any document sent by mail and dated only with a business postal meter will be considered filed on the date it is actually received by the Library of Congress.

(b) *Extensions.* A party seeking an extension must do so by written motion. Prior to filing such a motion, a party must attempt to obtain consent from the other parties to the proceeding. An extension motion must state:

(1) The date on which the action or submission is due;

(2) The length of the extension sought;

(3) The date on which the action or submission would be due if the extension were allowed;

(4) The reason or reasons why there is good cause for the delay;

(5) The justification for the amount of additional time being sought; and

(6) The attempts that have been made to obtain consent from the other parties to the proceeding and the position of the other parties on the motion.

PART 351—PROCEEDINGS

■ 8. The authority citation for part 351 continues to read as follows:

Authority: 17 U.S.C. 803.

■ 9. In § 351.1, revise paragraph (b)(4) to read as follows:

§ 351.1 Initiation of proceedings.

* * * * *

(b) * * *

(4) *Filing fee.* A petition to participate must be accompanied with a filing fee of $150 or the petition will be rejected. For petitions filed electronically through eCRB, payment must be made to the Copyright Royalty Board through the payment portal designated on eCRB. For petitions filed by other means, payment must be made to the Copyright Royalty Board by check or by money order. If a check is subsequently dishonored, the petition will be rejected. If the petitioner believes that the contested amount of that petitioner's claim will be $1,000 or less, the petitioner must so state in the petition to participate and should not include payment of the $150 filing fee. If it becomes apparent during the course of the proceedings that the contested amount of the claim is more than $1,000, the Copyright Royalty Judges will require payment of the filing fee at that time.

* * * * *

Dated: March 3, 2017.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2017–07928 Filed 4–19–17; 8:45 am]

BILLING CODE 1410–72–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0087; FRL–9959–54]

Deltamethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of deltamethrin in or on orange; citrus, dried pulp; citrus, oil. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 20, 2017. Objections and requests for hearings must be received on or before June 19, 2017, 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–2016–0087, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2016–0087 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 19, 2017. 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–2016–0087, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 18, 2016 (81 FR 71668) (FRL–9952–19), 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 5E8431) by Bayer CropScience, 2 T.W. Alexander Dr., Research Triangle Park, NC. The petition requested that 40 CFR 180.435 be amended by establishing tolerances for residues of the insecticide deltamethrin, (*S*)-cyano(3-phenoxyphenyl)methyl (1*R*,3*R*)-3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropanecarboxylate, in or on orange, fruit at 0.3 parts per million (ppm); orange, dried pulp at 3 ppm; orange, oil at 50 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the commodity definitions and tolerances as follows: ''Orange fruit'' proposed at 0.3 ppm shall be ''Orange'' at 0.30 ppm; ''Orange Dried Pulp'' at 3 ppm shall be ''Citrus, dried pulp'' at 3.0 ppm; and ''Orange Oil'' at 50 ppm shall be ''Citrus, oil'' at 50 ppm. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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.

Deltamethrin is classified as a Type II pyrethroid. Type II pyrethroids include an alpha-cyano moiety and induce a syndrome that includes pawing, burrowing, salivation, hypothermia, and coarse tremors leading to choreoathetosis. Neurotoxicity was observed throughout the database, and clinical signs characteristic of Type II pyrethroids, such as increased salivation, altered mobility/gait, and tremors, were the most common effects observed. Other observed neurotoxic effects included increased sensitivity to external stimuli, abnormal vocalization, and decreased fore- and hind-limb grip strength.

Chronic exposure does not result in accumulation or increased potency as a result of deltamethrin's rapid absorption, metabolism, and elimination. No observed adverse effect levels (NOAELs) for the acute and chronic studies are similar, and the acute endpoint is protective of the endpoints from repeat-dose studies. Only single-day risk assessments need to be conducted for purposes of endpoint selection and exposure assessment.

There were no indications of fetal toxicity in any of the guideline studies. Evidence of increased juvenile qualitative sensitivity was observed in the developmental neurotoxicity and 2-generation reproduction studies. However, the observations of increased sensitivity were at doses that were considered to be relatively high (*i.e.,* near lethal doses), whereas at doses near the point of departure, no effects on parental animals or offspring were observed in either the developmental neurotoxicity (DNT) or 2-generation reproduction study and, therefore, there is no susceptibility at these doses.

Deltamethrin is classified as ''not likely to be carcinogenic to humans.'' There was no evidence of carcinogenicity in either the rat or mouse long-term dietary studies up to the highest dose tested, nor was there any mutagenic activity in bacteria or cultured mammalian cells.

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 *http://www.regulations.gov* in document Deltamethrin: Human Health Risk Assessment for the Proposed Use of Deltamethrin on Oranges Without a U.S. Registration at page 24 in docket ID number EPA–HQ–OPP–2016–0087.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a

reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for deltamethrin used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DELTAMETHRIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure scenario	Point of departure	Uncertainty/FQPA safety factors	RfD, PAD, level of concern for risk assessment	Study and toxicological effects
Acute Dietary (≥6 years old)	Wolansky $BMDL_{1SD}$ = 1.49 mg/kg.	UF_A = 10X ..... UF_H = 10X FQPA SF = 1X	Acute RfD = 0.015 mg/kg. aPAD = 0.015 mg/kg/day	Wolansky BMD_{1SD} = 2.48 mg/kg based on decreased motor activity.
Acute Dietary (<6 years old)	Wolansky $BMDL_{1SD}$ = 1.49 mg/kg.	UF_A = 10X ..... UF_H = 10X FQPA SF = 3X	Acute RfD = 0.015 mg/kg. aPAD = 0.005 mg/kg/day	Wolansky BMD_{1SD} = 2.48 mg/kg based on decreased motor activity.
Chronic dietary (All populations).	A chronic endpoint is not necessary since increased toxicity is not observed with repeated dosing. The acute endpoint and doses are protective of longer-term exposure and risk.			
Incidental Oral (Short-term)	Wolansky $BMDL_{1SD}$ = 1.49 mg/kg.	UF_A = 10X ..... UF_H = 10X FQPA SF = 3X	Residential LOC for MOE = 300.	Wolansky BMD_{1SD} = 2.48 mg/kg based on decreased motor activity.
Dermal (short-term; all populations).	A dermal assessment was not conducted based on the lack of effects in a 21-day dermal study and low potential for dermal absorption for deltamethrin.			
* Inhalation (Short-term; ≥6 years old).	Wolansky $BMDL_{1SD}$ = 1.49 mg/kg.	UF_A = 10X ..... UF_H = 10X FQPA SF = 1X	Residential LOC for MOE = 100.	Wolansky BMD_{1SD} = 2.48 mg/kg based on decreased motor activity.
* Inhalation (Short-term; <6 years old).	Wolansky $BMDL_{1SD}$ = 1.49 mg/kg.	UF_A = 10X ..... UF_H = 10X FQPA SF = 3X	Residential LOC for MOE = 300.	Wolansky BMD_{1SD} = 2.48 mg/kg based on decreased motor activity.
Cancer (oral, dermal, inhalation).	Classification: ''Not likely to be Carcinogenic to Humans'' based on the absence of treatment related tumors in two adequate rodent carcinogenicity studies.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. * Inhalation absorption is assumed to be equivalent to oral absorption. BMD_{1SD} = The central estimate of the dose that results in decreased motor activity compared to control animals based upon a 1 standard deviation using Benchmark Dose Analysis. $BMDL_{1SD}$ = The 95% lower confidence limit of the central estimate. Wolansky = Reference to Wolansky *et al.* Acute Oral Toxicity in Rats, MRID #47885701.

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) 2003–2008 National Health and Nutrition Examination Surveys, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA acute dietary exposure is partially refined. Residues could result from agricultural uses and adulticide uses. Excluding the new orange tolerances, residue-level and percent crop treated assumptions have not changed since the previous rule, and those are discussed in the final rule published in the **Federal Register** of March 27, 2015 (80 FR 16296). For oranges, EPA used field trial values and the empirical processing factors for orange juice and citrus oil. In addition, HED used a percent crop treated estimate of 9%.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16. This software uses 2003–2008 food consumption data from the USDA's NHANES/WWEIA. Although a chronic dietary endpoint was not identified for deltamethrin, a chronic dietary exposure assessment was performed to provide background exposure for aggregation with short-term residential exposure. Residues could result from three different sources: Agricultural uses, food handling establishment uses, and adulticide uses. Assumptions about residue levels in food and percent crop treated for crops

except for oranges have not changed since the previous rule and are explained in the final rule published in the **Federal Register** of March 27, 2015 (80 FR 16296). For oranges, EPA used average field trial values and assumed 100% of imported oranges are treated with deltamethrin.

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

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

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing 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, the exposure estimate does not understate exposure for the population in such area.

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

The Agency estimated the PCT for acute exposure for existing uses as follows:

Apples: 2.5%; cantaloupes: 2.5%, carrots: 2.5%, cucumbers: 5%, pears: 5%, soybeans: 2.5%, tomatoes: 2.5%, watermelons: 2.5%.

The Agency estimated the PCT for chronic exposure for existing uses as follows:

Almonds: 1%; apples: 1%; globe artichokes: 40%; canola: 5%; cantaloupes: 1%; carrots: 1%; cotton: 1%; cucumbers: 2.5%; leeks: 2.5%; onions: 2.5%; pears: 2.5%; peppers: 5%; pistachios: 1%; potatoes: 1%; pumpkin: 1%; radishes: 1%; soybeans: 1%; squash: 1%; sunflowers: 2.5%; sweet corn: 1%; tomatoes: 1%; turnips: 1%; walnuts: 1%; watermelons: 1%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except for those situations in which the maximum PCT is less than one. In those cases, 2.5% is used as the maximum PCT. EPA uses an average PCT for chronic 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 one. In those cases, 1% is used as the average PCT.

The Agency estimated that 9% of domestically consumed oranges would be treated with deltamethrin as a result of the approval of the tolerances on oranges. Because there is currently no domestic use of deltamethrin on oranges, the Agency estimated the percentage of the domestic consumption of oranges that are imported. This calculation is based on three years of data (2011–2013) from USDA's Economic Research Service and assumes 100 percent of imported oranges are treated with deltamethrin. Because it is unlikely that all imported oranges will be treated with deltamethrin, the Agency believes that assuming 9% of oranges consumed have been treated with deltamethrin will not underestimate deltamethrin exposure on oranges.

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. 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 *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the First Index Reservoir Screening Tool (FIRST), Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of deltamethrin for acute exposures are estimated to be 0.20 parts per billion (ppb) for surface water and 0.20 ppb for ground water and chronic exposures for non-cancer assessments are estimated to be 0.20 ppb for surface water and 0.20 ppb for ground water. Both the acute and chronic surface and ground drinking water concentration were limited by the solubility of deltamethrin.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment and chronic dietary exposure assessment, the water concentration value of 0.20 ppb was used to assess the contribution to drinking water.

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

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. EPA assessed residential exposure using the Agency's 2012 Residential Standard Operating Procedures (SOPs) along with updates in policy regarding body weight in addition to the following assumptions: Since no treatment-related effects were observed at the limit dose, a dermal point of departure (POD) was not selected, and neither a handler nor a post-application dermal exposure assessment is required.

i. *Residential handler exposures.* Short-term residential handler inhalation exposure is anticipated from indoor and outdoor environments, and paint preservatives. Because no intermediate-term adverse effect was identified, deltamethrin is not expected to pose an intermediate-term risk.

ii. *Residential post-application exposures.* Post-application inhalation exposure for adults and children is anticipated to be negligible for indoor (spot, crack and crevice) and outdoor (turf, garden and trees) environments, pet collars and paints; therefore, a quantitative assessment was not performed. EPA assessed post-application short-term incidental oral exposures to children for representative indoor/outdoor and pet incidental oral scenarios including hand-to-mouth, object-to-mouth, soil ingestion, and episodic granule ingestion scenarios. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Deltamethrin is included in the pyrethroid/pyrethrin cumulative risk assessment (CRA). The new tolerances to cover residues of deltamethrin on imported oranges, citrus oil and citrus pulp has an insignificant impact on the CRA. In the cumulative assessment, residential exposure was the greatest contributor to the total exposure. Although there are residential uses for deltamethrin, the proposed use will have no impact on the residential component of the cumulative risk estimates. Dietary exposures make a minor contribution to the total pyrethroid exposure, and as a result, the new use on oranges would have an insignificant impact on the cumulative dietary risk.

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 Safety Factor (FQPA 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 is no quantitative and/or qualitative evidence of increased susceptibility of rat or rabbit fetuses to in utero exposure to deltamethrin. However, potential qualitative susceptibility was observed at high doses in the DNT and 2-generation reproduction study for juveniles. In addition, pyrethroid pharmacokinetics literature indicates an increased quantitative susceptibility for children less than 6 years of age.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF reduced to 1X for assessing risks to adults and children 6 years of age and older and to 3X for assessing risks to children less than 6 years of age. That decision is based on the following findings:

i. The toxicity database is considered complete for deltamethrin with respect to guideline studies; it includes, among other studies, developmental toxicity studies in rats and rabbits, a reproduction study in rats, and acute neurotoxicity (ACN), subchronic neurotoxicity (SCN), and developmental neurotoxicity (DNT) studies. Nevertheless, EPA lacks additional data to fully characterize the potential for juvenile sensitivity to many pyrethroids, including deltamethrin. For this assessment, EPA considered the standard guideline studies as well as numerous studies from the scientific literature that describe the pharmacodynamic (PD) and pharmacokinetic (PK) profile of the pyrethroids in general. Many of these studies were conducted with deltamethrin.

ii. 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.

iii. Evidence of increased juvenile qualitative sensitivity was observed in the developmental neurotoxicity and 2-generation reproduction studies. However, the observations of increased sensitivity were at doses that were considered to be relatively high (*i.e.,* near lethal doses), whereas at doses near the point of departure, no effects on parental animals or offspring were observed in either the DNT or 2-generation reproduction study, and therefore, there is no susceptibility at these doses. The Agency has retained a 3X uncertainty factor to protect for exposures of children less than 6 years of age based on increased quantitative susceptibility seen in studies on pyrethroid pharmacokinetics (primarily conducted with deltamethrin) and the increased quantitative juvenile susceptibility observed in high dose guideline and literature studies with deltamethrin and other pyrethroids. The Agency has no residual uncertainties regarding age-related sensitivity for women of child bearing age as well as for all adult populations and children 6 years of age and older, based on the absence of pre-natal sensitivity observed in 76 guideline studies for 24 pyrethroids and the scientific literature. Additionally, no evidence of increased quantitative or qualitative susceptibility was seen in the pyrethroid scientific literature related to pharmacodynamics.

iv. There are no residual uncertainties identified in the exposure databases. The dietary exposure assessments are based on reasonable to high-end 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. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to deltamethrin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by deltamethrin.

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 86% of the aPAD for children 3–5 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Based on the data summarized in Unit III.A., there is no increase in hazard with increasing dosing duration. Furthermore, chronic dietary exposures will be lower than acute 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, including inhalation and hand-to-mouth (for children only), result in aggregate MOEs of 2,300 for the U.S. Population; 2,600 for females ages 13–49; and 490 for children 1–2 years old. Because EPA's level of concern for deltamethrin is a MOE of 100 for the U.S. population and females 13–49, and 300 for children 1–2 years old or below, these MOEs are not of concern.

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

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, 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)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

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

The Codex has established MRLs for deltamethrin in or on citrus fruits at 0.02 ppm. These MRLs are different than the tolerances being established for deltamethrin in the United States. Harmonization of the 0.30 ppm tolerance with the lower Codex MRL of 0.02 ppm is not possible because the maximum residue value in oranges was 0.18 ppm, which is considerably higher than the Codex MRL.

C. Revisions to Petitioned-For Tolerances

The Agency added a significant figure to the proposed tolerance level for orange and citrus, dried pulp to prevent violative samples from being considered non-violative. For example, if a sample contained a residue level of 0.34 ppm, it would have a violative residue if the tolerance is set at 0.30 ppm. In addition, the Agency is revising the commodity terminology to be consistent with the Agency's commodity vocabulary.

V. Conclusion

Therefore, tolerances are established for residues of deltamethrin, (*S*)-cyano(3-phenoxyphenyl)methyl (1*R*,3*R*)-3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropanecarboxylate, in or on orange at 0.30 ppm; citrus, dried pulp at 3.0 ppm; citrus, oil at 50 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as

the 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 21, 2017.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.435, paragraph (a)(1):

■ i. Add alphabetically the entries ''Citrus, dried pulp,'' ''Citrus, oil,'' and ''Orange'' to the table; and

■ ii. Revise the footnote at the end of the table.

The additions and revision read as follows:

§ 180.435 Deltamethrin; tolerance for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Citrus, dried pulp *	3.0
Citrus, oil *	50
* * * * *	
Orange *	0.30
* * * * *	

* There are no U.S. registrations.

* * * * *

[FR Doc. 2017–07816 Filed 4–19–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 25, 73, and 74

[GN Docket No. 15–236; FCC 16–128]

Review of Foreign Ownership Policies for Broadcast, Common Carrier and Aeronautical Radio Licensees

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, information collection requirements adopted in the Commission's Report and Order, FCC 16–128. This document is consistent with the Report and Order, which stated that the Commission would publish a document in the **Federal Register** announcing OMB approval and the effective date of the rules.

DATES: This final rule is effective on April 20, 2017. The amendments to 47 CFR 1.5000 through 1.5004, 25.105, 73.1010 and 74.5, published at 81 FR 86586, December 1, 2016, are effective on April 20, 2017.

FOR FURTHER INFORMATION CONTACT: Cathy Williams by email at *Cathy.Williams@fcc.gov* and telephone at (202) 418–2918.

SUPPLEMENTARY INFORMATION: This document announces that, on April 9, 2017, OMB approved information collection requirements contained in the Commission's Report and Order, FCC 16–128, published at 81 FR 86586. The OMB Control Number is 3060–1163. The Commission publishes this notice as an announcement of the effective date of those information collection requirements.

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on April 9, 2017, for the information collection requirements contained in 47 CFR 1.5000 through 1.5004, 25.105, 73.1010 and 74.5, as amended, in the Commission's Report and Order, FCC 16–128. Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–1163.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1163.

OMB Approval Date: April 9, 2017.

OMB Expiration Date: April 30, 2020.

Title: Regulations Applicable to Broadcast, Common Carrier and Aeronautical Radio Licensees Under Section 310(b) of the Communications Act of 1934, as amended.

Form Number: N/A.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 81 respondents; 81 responses.

Estimated Time per Response: 2 hours–46 hours.

Frequency of Response: On-occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory