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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0209; FRL-9924-60]

Deltamethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide deltamethrin in or on all food and feed commodities from use of deltamethrin as a wide-area mosquito adulticide. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0209, 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: Susan Lewis, 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 Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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-2014-0209 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2014-0209, 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 January 28, 2015 (80 FR 4527) (FRL-9921-60), 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 [3F8210]) by Bayer CropScience, 2 T.W. Alexander Dr. Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.435 be amended by establishing a tolerance for residues of the insecticide deltamethrin, (1R,3R)-R-cyano(3-phenoxyphenyl)methyl 3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropanecarboxylate, in or on food and feed commodities at 0.05 parts per million (ppm) from use as a wide-area mosquito adulticide. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received on the notice of filing. EPA's response to the comment is discussed 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, a Type II pyrethroid, targets the nervous system by disrupting the voltage-gated sodium channels, resulting in neurotoxicity. Neurotoxicity was observed throughout the toxicity database, and

effects were seen across species, sexes, exposure duration, and routes of administration. Clinical signs characteristic of Type II pyrethroids, such as increased salivation, altered mobility/gait, and tremors were the most common effects observed. Increased sensitivity to external stimuli, abnormal vocalization, and decreased fore- and hind-limb grip strength were also commonly observed in the database.

Deltamethrin is rapidly absorbed following an oral dose, and effects are typically observed within two to five hours after dosing. For pyrethroids, as a class, the combination of rapid absorption, metabolism, and elimination precludes accumulation and increased potency following repeated dosing. This is also true of deltamethrin. 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 dosing studies.

A dermal risk assessment was not conducted based on the lack of effects in a 21-day dermal study and low potential for dermal absorption for deltamethrin. These findings are consistent with the toxicology profile of many pyrethroids.

Deltamethrin did not have any adverse effects on fetuses or offspring in the prenatal developmental studies in rats and rabbits. However, potential qualitative susceptibility was observed at high doses in the developmental neurotoxicity study (DNT) and the 2-generation reproduction study. Symptoms included vocalization, decreased pre- and post-weaning body weight in pups of both sexes, decreased body weight and body weight gain in maternal animals, hyperactivity, and excessive salivation. The increased qualitative susceptibility in the DNT and 2-generation reproduction study was observed at doses 10- to 20-fold higher (near lethal doses) than the current points of departure (PODs) selected for risk assessment. At doses near the POD, no effects on parental animals or offspring were observed in either the DNT or 2-

generation reproductive studies. Therefore, the current PODs are protective of the observed sensitivity.

There was no evidence of immunotoxicity after deltamethrin exposure in the toxicology database or in an immunotoxicity study in rats. Deltamethrin is classified as "not likely to be carcinogenic to humans." 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.

The database shows that deltamethrin has moderate to minimal acute toxicity via the oral route, moderate acute toxicity via the inhalation route, and minimal acute toxicity via the dermal route of exposure. Deltamethrin is minimally irritating to the eyes, non-irritating to the skin, and is not a skin sensitizer.

The Agency is making best use of the extensive scientific knowledge about the mode of action/adverse outcome pathway (MOA/AOP) on pyrethroids in the risk assessments for this class of pesticides. A significant portion of the scientific literature on pyrethroids utilizes deltamethrin as the test chemical. In the on-going work by the Council for the Advancement of Pyrethroid Human Risk Assessment (CAPHRA), deltamethrin is one of two sentinel pyrethroids being used to develop the initial, extensive database of *in vitro* and *in vivo* toxicology studies and highly refined physiologically-based pharmacokinetic (PBPK) models. Pharmacokinetics (PK) can be defined as what the body does to the chemical. The underlying PK of pyrethroids is an important determination of their toxicity because the concentration of pyrethroid at the sodium channel relates to the extent of toxicity; greater pyrethroid concentration translates as increased neurotoxicity. Age-dependent PK differences have been identified for several pyrethroids (i.e., there are differences in the ability of adults and juveniles to metabolize

pyrethroids). The enzymes that metabolize and detoxify pyrethroids are present in rats and humans at birth, and as a result, both juveniles and adults are able to tolerate low doses of pyrethroids when the internal dose, or the amount of pyrethroid at the sodium channel, is low. However, the activity of these enzymes increases with age, conveying in adults a greater capacity to detoxify pyrethroids compared to juveniles and the PK contribution to the FQPA Safety Factor will be 1X for adults and children >6 years old, and 3X for children <6 years old.

Pharmacodynamics (PD) can be defined as the changes that chemicals cause to the body, in this case, how pyrethroids interact with the sodium channels. In contrast to the age-related PK differences identified for pyrethroids, pharmacodynamic contributions to pyrethroid toxicity are not age-dependent. The occurrence and ontogeny of voltage-gated sodium channels in humans are not well characterized compared to those in the rat. The available data indicate that the rat is a highly-sensitive model and extrapolations from the rat would be protective of human health. Based on the comparable function and distribution of sodium channels between the species, the rat is an appropriate surrogate for the evaluation of human PD. Based on the body of data, the Agency concludes that juvenile rats are not more sensitive than adults with respect to pyrethroid PD, and the PD contribution to the FQPA SF will be 1X.

The Wolansky et al. acute oral study (2006), in which decreased motor activity was observed, provides the most robust data set for extrapolating risk from exposure to deltamethrin. The dose used for risk assessment was determined using a benchmark dose (BMD) analysis using one standard deviation from the control group as the benchmark response (BMR) as suggested for continuous endpoints in the Agency's BMD guidance (USEPA 2012). The Wolansky acute study, endpoint, and dose were used for all dietary (acute), non-occupational (incidental oral and inhalation), and occupational exposure (inhalation) scenarios because it was

the most robust data set for extrapolating risk from deltamethrin, and there is a lack of increased hazard from repeated/chronic exposure to deltamethrin.

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 as a Mosquito Adulticide over Agricultural Crops* at [page 55] in docket ID number EPA-HQ-OPP-20[14]-[0209].

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://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for deltamethrin used for human risk assessment is discussed in Unit III.B of the final rule published in the Federal Register of [November 7, 2014] ([79] FR [66294]) (FRL-9918-24).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to deltamethrin, EPA considered exposure under the petitioned-for tolerance as well as all existing deltamethrin tolerances in 40 CFR 180.435. Acute and chronic dietary (food and drinking water) exposure assessments were conducted using 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 U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). Specific information on the dietary exposure assessment can be found at http://*www.regulations.gov* in document *Deltamethrin. Acute and Chronic Dietary (Food and Drinking Water) Exposure and Risk Assessment for the Proposed Use of Deltamethrin as a Wide Area Mosquito Adulticide over Agricultural Crops* in docket ID number EPA-HQ-OPP-20[14]-[0209].

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. As to residue levels in food, EPA used tolerance-level residues for most commodities and Pesticide Data Program (PDP) monitoring data for a number of commodities. Maximum percent crop treated (%CT) estimates were used for some commodities. To account for the mosquito adulticide use, the maximum residue value from the mosquito adulticide trials was multiplied by the %CT estimate for the adulticide use (1%) for those commodities that

would only have a residue as a result of the mosquito adulticide use. However, if the commodity could have residues from both the agricultural and mosquitocide uses, residue values from the adulticide trials were included in a distribution considering the 1% CT estimate (depending on whether the commodities were blended, nonblended, or partially blended). Default processing factors were used for some processed commodities and empirical factors were used for others.

ii. *Chronic exposure*. As to residue levels in food, EPA [used tolerance-level residues for most commodities. The average PDP value was used for cereal grains and milk. The average mosquito adulticide residue value multiplied by the 1% CT estimate was used to account for the mosquito adulticide uses. Since deltamethrin is registered for use in food handling establishments (FHEs), one-half the FHE tolerance was used to account for the FHE uses. The FHE tolerance is based on the LOQ, and one-half the tolerance was used as a refinement in the dietary assessment. For the commodities for which one-half the FHE tolerance was used, 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. Default processing factors were used for some processed commodities and empirical factors were used for others.

The chronic assessment was conducted solely for the purpose of obtaining estimates of background levels of dietary exposure for estimating aggregate risk.

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 existing uses as follows: For acute dietary: 2.5% for apples, cantaloupes, carrots, soybeans, tomatoes, and watermelons; and 5% for cucumbers and

pears. For chronic dietary: 1% for apples, cantaloupes, carrots, cotton, potatoes (some food forms), pumpkins, radishes, squash, tomatoes, turnips, and watermelon; 2.5% for cucumbers, leeks, onions, pears, and sunflowers; 4.65% (commodities with residues resulting only from the FHE use) for: almonds, pistachios, potatoes (some food forms), soybeans, sweet corn, and walnuts; 5% for canola and peppers; and 40% for globe artichokes.

In the acute and chronic assessments, the mosquito adulticide %CT estimate of 1% was used to modify the mosquito adulticide use residue value. Residues from the mosquito adulticide use were included for all commodities with the exception of livestock commodities because the livestock commodities tolerances are very conservative, and any residues in livestock feed items resulting from the mosquito adulticide use will not increase the established tolerance levels.

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 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 and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency 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 *http://www.epa.gov/oppefed1/models/water/index.htm*.

The estimated drinking water concentration (EDWC) of deltamethrin for acute and chronic exposures is estimated to be 0.200 parts per billion (ppb) for both surface water and ground water. The FIRST Model was used to determine the surface water concentration, and the SCI-GROW Model was used to determine the groundwater concentration. The acute surface

water EDWC and the groundwater EDWC were equivalent because, in both cases, the value was limited by the solubility of deltamethrin.

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

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: residential outdoor and indoor sites, turf, paint additives, and pet products.

There are no residential handler exposure scenarios associated with the proposed mosquito control use as applications are to be made by Federal, State, Tribal or local Government Officials or the U.S. Military. However, there is potential for residential post-application exposure resulting from mosquito control use. Post-application inhalation exposures and incidental oral (hand-to-mouth) contact with residues deposited on lawn/turf from ULV truck fogger applications were included in the quantitative risk assessment. To calculate post-application exposure from ULV truck fogger applications, EPA used the 2012 Residential SOPs for Outdoor Fogging/Misting Systems, with minimal modification to the well-mixed box (WMB) model. The WMB model allows for the estimation of inhalation exposure in the breathing zones of adults and children residing in areas being treated by ground application of deltamethrin.

EPA also assessed handler and post-application exposures for existing residential uses of deltamethrin (i.e., indoor, outdoor, pet, and paint additive). A quantitative dermal

assessment for residential handlers was not conducted since no systemic toxicity associated with dermal exposure to deltamethrin was observed. MOEs were calculated for the inhalation route of exposure only. Adult post-application exposures from the existing uses were not quantitatively assessed since inhalation exposures are typically negligible in outdoor settings. Post-application inhalation exposure for adults and children is anticipated to be negligible for representative residential registered uses; therefore, a quantitative post-application inhalation exposure assessment was not performed. EPA assessed post-application 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://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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: the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. The cumulative risk assessment (CRA) for the pyrethroids/pyrethrins (published on 11/9/2011 and available at http://www.regulations.gov; EPA-HQ-OPP-2011-0746)

did not identify cumulative risks of concern, allowing the Agency to consider new uses for pyrethroids. Deltamethrin was included in the pyrethroid/pyrethrin CRA.

Dietary exposures make a minor contribution to the total pyrethroid exposure. The dietary exposure assessment performed in support of the pyrethroid CRA was much more highly refined than that performed for deltamethrin alone. Additionally, the PODs selected for deltamethrin are specific to deltamethrin, whereas the PODs selected for the cumulative assessment were based on common mechanism of action data that are appropriate for all 20 pyrethroids included in the CRA. Dietary exposure to deltamethrin residues resulting from the proposed wide-area mosquito adulticide use will contribute very little to the dietary exposure to deltamethrin alone and will have an insignificant impact on the 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. In order to determine if the registered deltamethrin indoor and turf uses will significantly contribute to, or change the overall findings in the pyrethroid CRA, the Agency performed a quantitative exposure and risk assessment. This assessment used the deltamethrin relative potency factor (RPF) as well as the same exposure algorithms and inputs that were used in the 2011 pyrethroid CRA. In all cases, the estimated deltamethrin MOEs using the RPF method were higher (i.e., less of a risk concern) than those used in the 2011 pyrethroid CRA. Thus, the Agency continues to support the previous assessment, and concludes that the registered deltamethrin uses will not significantly contribute to the overall findings in the 2011 pyrethroid CRA, and the registered deltamethrin indoor and turf uses will have no impact on the residential component of the cumulative risk estimates.

For information regarding EPA's efforts to evaluate the risk of exposure to this class of chemicals, refer to: http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.

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 FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There were no indications of fetal toxicity in any of the guideline studies. Evidence of increased juvenile qualitative sensitivity was observed in the DNT and 2-generation reproduction studies at doses that were considered to be relatively high (i.e., near lethal doses). However, 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.

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 to 3X for infants and children < 6 years old; and to 1X for children > 6 years old, women of child bearing age and all adult populations. That decision is based on the following findings:

i. The database of experimental toxicology studies available for deltamethrin is largely complete including developmental toxicity studies in rats and rabbits, a reproduction study in rats, and acute neurotoxicity (ACN), subchronic neurotoxicity (SCN), and developmental neurotoxicity (DNT) studies. The database provides a robust characterization profile for children 6 years old and older, as well as for adults. In addition to the standard guideline studies, numerous studies from the scientific literature that describe the pharmacodynamic and pharmacokinetic profile of the pyrethroids in general have been considered in this assessment. Many of these studies were conducted with deltamethrin. A 28- or 90-day inhalation study is not available, but the Agency determined the study is not required for 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. There were no indications of fetal toxicity in any of the guideline studies in the database, 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. These observations are consistent with the findings of juvenile sensitivity in the literature for deltamethrin. 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. The Agency has retained a 3X uncertainty factor to protect for exposures of children <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, 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 with regard to dietary exposure. The dietary exposure assessments are based on high-end residue levels for most commodities, and 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 81% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. A chronic dietary risk assessment was not conducted because there is no apparent increase in hazard from repeated/chronic exposures to deltamethrin. Therefore, the acute endpoint is protective of the endpoints from repeat dosing studies. A chronic dietary exposure assessment was performed in order to generate background exposure estimates to aggregate with residential exposure estimates for the short-term aggregate risk assessment.

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 aggregate MOEs of 2,500 for the general U.S. population and of 520 for children 1-2 years old, the population group receiving the greatest exposure. Because EPA's level of concern for deltamethrin is an MOE of 300 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. 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 utilizing gas chromatography with electron capture detection (GC/ECD), is available for enforcing tolerances for residues of deltamethrin in plant commodities, as described in Pesticide Analytical Manual (PAM) Volume II, Section 180.422. Another GC/ECD method (Method HRAV-22) is available for enforcing tolerances in livestock commodities. Adequate confirmatory method validation data have been submitted for these methods, along with adequate independent laboratory validation (ILV) trials.

Multiresidue methods data for *cis*-deltamethrin and *trans*-deltamethrin were previously sent to FDA. *Cis*-deltamethrin is completely recovered through Methods 302 and 303, and partially recovered through Method 304. *Trans*-Deltamethrin is partially recovered through Method 303, but not recovered through Method 304.

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.

Harmonization of MRLs is not an issue for the proposed use of deltamethrin as a wide area mosquitocide since established tolerance levels are not changing.

C. Response to Comments

An anonymous citizen objected to the approval of the requested tolerance for deltamethrin. The commenter expressed concerns about the neurotoxicity of the chemical and made unsubstantiated claims that together with all other approved toxic chemicals, use of deltamethrin could lead to many deaths and injuries and that the Agency is harming the American people. Under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances where the safety standard imposed by that statute is met. When new or amended tolerances for residues of a pesticide in food or feed are requested, the Agency evaluates whether there is a reasonable certainty of no harm from aggregate exposure to the pesticide chemical residue. The risk assessment conducted by the Agency considers the potential risks from dietary exposure and other non-occupational

exposures. The Agency also considers the available information regarding cumulative toxicological effects of the pesticide residues and other substances that share a common mechanism of toxicity with the subject pesticide. Such an assessment has been conducted for deltamethrin. Deltamethrin is a Type II pyrethroid, and as with other pyrethroids, deltamethrin causes neurotoxicity. These effects are well characterized and adequately assessed by the body of data available to the Agency. The Agency is confident that it has chosen endpoints, points of departure, and uncertainty factors, that have a strong scientific foundation and that are protective for all human populations. As a result, EPA concludes that the tolerances for deltamethrin are safe.

V. Conclusion

Therefore, tolerances are established for residues of deltamethrin, (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylic acid (S)-alpha-cyano-3-phenoxybenzyl ester and its major metabolites, *trans*-deltamethrin (S)-*alpha*-cyano-m-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate and *alpha*-R-deltamethrin[(R)-*alpha*-cyano-m-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate in or on all food/feed items (other than those covered by a higher tolerance as a result of use on growing crops) from use as a wide-area mosquito adulticide at 0.05 ppm.

Currently, a tolerance of 0.05 ppm is established for residues of deltamethrin in or on all food/feed items (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments. The tolerance level does not need to be increased for the proposed use as a mosquito adulticide; however, EPA is revising 40 CFR 180.435 to clarify the tolerance. In addition, EPA is removing subparagraphs (a)(2)(i), (ii), (A) and (B) as they

contain language that is more appropriately enforced under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as use directions on the label.

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 18, 2015.

Susan Lewis,

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)(2) is revised to read as:

§ 180.435 Deltamethrin; tolerances for residues.

(a) ***General*****. * * ***

* * * * *

(2) A tolerance of 0.05 ppm is established for residues of the insecticide deltamethrin, including its metabolites and degradates, in or on all food/feed items (other than those covered by a higher tolerance as a result of use on growing crops) when deltamethrin is used in food/feed handling establishments or as a wide-area mosquito adulticide. Compliance with the tolerance levels specified is to be determined by measuring only deltamethrin, (1*R,*3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylic acid (*S*)-*alpha*-cyano-3-phenoxybenzyl ester, and its major metabolites, *trans*-deltamethrin, (*S*)-*alpha*-cyano-*m*-phenoxybenzyl(1*R,*3*S*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate, and *alpha*-*R*-deltamethrin, (*R*)-*alpha*-cyano-*m*-phenoxybenzyl-(1*R,*3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate, in or on the commodity.

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