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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: October 16, 2014.

**Daniel J. Rosenblatt,**

*Acting 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 § 180.205:

■ a. In the table for paragraph (a), remove the entries for ''Ginger'' and ''Potato'' and add alphabetically the entry ''Vegetable, tuberous and corm, subgroup 1C'';

■ b. In the table for paragraph (c), remove the entries for and ''Cassava,'' ''Tanier,'' and ''Yam, true, tuber''.

The addition reads as follows:

**§ 180.205 Paraquat; tolerances for residues.**

(a) * * *

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Vegetable, tuberous and corm, subgroup 1C | 0.50 |
| * * * * * | |

* * * * *

[FR Doc. 2014–25592 Filed 10–28–14; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[EPA–HQ–OPP–2013–0659; FRL–9917–30]**

## Prallethrin; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of the insecticide prallethrin, including its metabolites and degradates, in or on all food commodities from use of prallethrin in food handling establishments where food and food products are held, processed, prepared and/or served, or as a wide-area mosquito adulticide at 1.0 part per million (ppm). McLaughlin Gormley King Company requested these tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective October 29, 2014. Objections and requests for hearings must be received on or before December 29, 2014, 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–2013–0659, 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:** Daniel J. Rosenblatt, Registration Division (RD) (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; 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 section 408(g) of FFDCA, 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–2013–0659 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before December 29, 2014. 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–2013–0659, 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.htm.* 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 25, 2013 (78 FR 63938) (FRL–9901–96), EPA issued a document pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8090) by McLaughlin Gormley King Company, 8810 Tenth Avenue, Minneapolis, MN 55427. The petition requested that 40 CFR 180.545 be amended by establishing a tolerance of 1.0 ppm for residues of the insecticide prallethrin, including its metabolites and degradates, in or on all raw agricultural commodities and processed food, and food products in food handling establishments where food and food products are held, processed, prepared and/or served, or as a wide-area mosquito adulticide. That document referenced a summary of the petition prepared by McLaughlin Gormley King Company, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

## 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 prallethrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with prallethrin 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.

Prallethrin is a member of the pyrethroid class of insecticides. Pyrethroids have historically been classified into two groups, Type I and Type II, based upon chemical structure and neurotoxicological effect. Type I pyrethroids lack an alpha-cyano moiety and induce a syndrome consisting of aggressive sparring, altered sensitivity to external stimuli, and fine tremor progressing to whole-body tremor and prostration in rats. These Type I pyrethroid-specific behaviors are collectively described as the T-syndrome. Type II pyrethroids contain an alpha-cyano moiety and produce a syndrome that includes pawing, burrowing, salivation, and coarse tremors leading to choreoathetosis in rats. These Type II pyrethroid-specific behaviors are collectively described as the CS-syndrome (Verschoyle and Aldridge 1980; Lawrence and Casida 1982). Prallethrin is structurally similar to Type I pyrethroids. The adverse outcome pathway (AOP) shared by pyrethroids involves the ability to interact with voltage-gated sodium channels (VGSCs) in the central and peripheral nervous system, leading to changes in neuron firing, and ultimately neurotoxicity.

Prallethrin has been evaluated for a variety of toxic effects in experimental toxicity studies. Neurotoxicity was observed throughout the database and is the most sensitive endpoint. Effects were seen across species, sexes, and routes of administration. In the acute rat neurotoxicity study, decreased exploratory behavior was seen at the time of peak effect. Reduced motor activity and transient tremors were also observed in the study. In the subchronic rat neurotoxicity study, a higher arousal rate was observed in animals at the highest dose tested. Clinical signs of neurotoxicity were also observed in other toxicity studies (subchronic and chronic oral studies in dogs, developmental toxicity studies in the rat and rabbit, 21-day dermal and 28-day inhalation studies in rats). No neurotoxic effects were observed in rats in the chronic toxicity study.

Effects were also observed in the liver (rats, mice, and dogs), heart (dogs), and thyroid gland (rats). Some effects were also seen in the kidney (mice and rats). However, neurotoxicity was the most sensitive endpoint in the toxicology database, and other effects were generally seen in the presence of neurotoxicity and/or at higher doses. Liver effects observed included increased weight, elevated serum cholesterol and alkaline phosphatase

activity, centrilobular hepatocyte vacuolation, histiocytic infiltration, enlarged liver, and perilobular hepatocellular hypertrophy. In dogs, myocardial fiber degeneration was seen in females in the subchronic study at the highest dose tested. Heart effects were also seen in one mid-dose female in the chronic study (hemorrhage and red discoloration). However, there was no dose response for the observed heart lesions in the study. Thyroid effects were observed in rats and consisted of increases in the number of small follicles and follicular cell hypertrophy and hyperplasia. The thyroid effects were seen in short-term studies in the presence of liver effects. Kidney effects observed were increased weights and histopathology.

Developmental and reproduction studies are available for prallethrin. There was no evidence of increased quantitative or qualitative susceptibility in any of the studies. In the developmental studies, no toxic effects were noted in fetuses up to the highest doses tested. Maternal effects in the studies included tremors, salivation, exaggerated reflexes, and chromorhinorrhea. In the reproduction study, decreased pup body weights were seen during the lactation period. Effects seen in parental animals were decreased body weights and body weight gains, increased liver weights and microscopic findings in the liver, kidney, thyroid, and pituitary.

Prallethrin is classified as ''Not Likely to be Carcinogenic to Humans.'' No tumors were observed in rat and mouse carcinogenicity studies up to the highest doses tested. In both the rat and mouse studies, the animals could have tolerated higher dose levels; however, EPA determined that dose levels were adequate to assess potential carcinogenicity.

Prallethrin tested negative in the majority of the genotoxicity studies. It also tested negative in an *in vitro* chromosomal aberration study in Chinese Hamster Ovary (CHO K1) cells without metabolic activation, but tested positive at all doses with metabolic activation. However, clastogenicity was not clearly dose-related, was seen at nontoxic and slightly toxic doses, and was not expressed in *in vivo* studies and structure-activity comparisons with the other pyrethroids revealed no correlations with clastogenicity. Other gene mutation, chromosomal aberration, and unscheduled DNA synthesis (UDS) studies were negative; therefore, there is no concern for genotoxicity.

Acute lethality studies conducted with prallethrin indicate moderate acute toxicity via the oral and inhalation routes of administration (Category II) and low acute toxicity via the dermal route (Categories IV). It is not irritating to the skin (Category IV) but is minimally irritating to the eye (Category IV). It is not a dermal sensitizer. The weight of evidence from the available guideline, non-guideline, mechanism of action, and pharmacokinetics studies supports characterizing the toxicological profile of pyrethroids, including prallethrin, as being rapid in onset and associated with acute, peak exposures. Also, there is no apparent increase in hazard from repeated/chronic exposures to prallethrin.

Specific information on the studies received and the nature of the adverse effects caused by prallethrin 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 in the document titled ''*Prallethrin: Human Health Risk Assessment for the Tolerance Petition to Amend the Section 3 Mosquito Adulticide Registration to Include Use of the Insecticide Over All Crops,*'' dated September 15, 2014, by going to *http://www.regulations.gov.* The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2013–0659. Double-click on the document to view the referenced information.

*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 (LOC) 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 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 prallethrin used for human risk assessment are shown in Tables 1 and 2 of this unit. Based on the proposed use patterns for prallethrin, endpoints and points of departure were selected for dietary (acute only), dermal, inhalation, and incidental oral exposures.

For oral exposures (acute dietary and incidental oral), the endpoint and POD were selected from a chronic dog study in which neurotoxicity was observed within 4 weeks of dosing and was considered to have potentially resulted from a single dose, based on a weight-of-the-evidence. For dermal assessment, the endpoint was selected from the route-specific 21-day dermal study in the rat, in which clinical signs were observed within 1 to 3 days of dosing. The endpoints being used to assess oral and dermal exposures are the same (neurotoxicity); therefore, risks from those routes of exposure were combined. Although the LOAEL for inhalation is also based on neurotoxicity, derivation of the human equivalent concentrations (HECs) used for inhalation risk assessment shows that assessing inhalation exposure based on the portal-of-entry effects is protective of the systemic endpoints, including neurotoxicity. As a result, inhalation exposure was not combined with either the dermal or the oral routes of exposure.

A chronic dietary risk assessment was not conducted for prallethrin. Given what is known about pyrethroid toxicokinetics/dynamics, in general, and as there is no apparent increase in hazard from repeated/chronic exposures to prallethrin, the acute dietary exposure assessment is protective of chronic dietary exposures. Based on the toxicity profile, intermediate- or long-term exposure assessments were not conducted for adults or children.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PRALLETHRIN FOR USE IN DIETARY AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS

| Exposure/scenario | Point of departure and uncertainty/ FQPA safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|---|---|---|---|
| Acute Dietary (Children ≥6 years old and Adults). | NOAEL = 2.5 mg/kg/day.<br>$UF_A$ = 10×<br>$UF_H$ = 10×<br>FQPA SF = 1× | Acute RfD = 0.025 mg/kg/day.<br>aPAD= 0.025 mg/kg/day. | Chronic dog study (capsule). LOAEL = 5 mg/kg/day based on clinical signs of neurotoxicity. |
| Acute Dietary (Children <6 years old). | NOAEL = 2.5 mg/kg/day.<br>$UF_A$ = 10×<br>$UF_H$ = 10×<br>FQPA SF = 3× | Acute RfD = 0.025 mg/kg/day.<br>aPAD= 0.008 mg/kg/day | |
| Incidental Oral Short-Term (1 to 30 days). | NOAEL = 2.5 mg/kg/day.<br>$UF_A$ = 10×<br>$UF_H$ = 10×<br>FQPA SF = 3× | Residential LOC for MOE = 300. | |
| Dermal Short-term (1 to 30 days) (Children <6 years old). | Dermal NOAEL = 30 mg/kg/day.<br>$UF_A$ = 10×<br>$UF_H$ = 10×<br>FQPA SF = 3× | Residential LOC for MOE = 300. | 21-day Dermal Rat. LOAEL = 150 mg/kg/day based on observed clinical signs of toxicity (fixation, abnormal gait, tremors, sensitivity to external stimuli, vocalization, twitching and writhing spasms), all beginning between days 1 and 3 of a 21-day dermal study in rats. |
| Dermal Short-term (1 to 30 days) (Children ≥6 years old and Adults). | Dermal NOAEL = 30 mg/kg/day.<br>$UF_A$ = 10×<br>$UF_H$ = 10×<br>FQPA SF = 1× | Residential LOC for MOE = 100. | |
| Inhalation Short-term (1 to 30 days) (Children <6 years old). | Inhalation NOAEL = 0.001 mg/L.<br>$UF_A$ = 3×<br>$UF_H$ = 10×<br>FQPA SF = 3×<br>HEC/HED calculations used for risk assessment (see below) | Residential LOC for MOE = 100. | 28-Day Inhalation Rat. LOAEL = 0.0044 mg/L based on irregular respiration, decreased spontaneous activity, salivation, incontinence, and nasal discharge. |
| Inhalation Short-term (1 to 30 days) (Children ≥6 years old and Adults). | Inhalation NOAEL = 0.001 mg/L.<br>$UF_A$ = 3×<br>$UF_H$ = 10×<br>FQPA SF = 1×<br>HEC/HED calculations used for risk assessment | Residential LOC for MOE = 30. | |

aPAD = acute population adjusted dose. FQPA SF = FQPA Safety Factor. HEC = human equivalent concentration. HED = human equivalent dose. LOAEL = lowest observed adverse effect level. LOC = level of concern. MOE = margin of exposure. NOAEL = no observed adverse effect level. 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. RfD = reference dose. UF = uncertainty factor. $UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = potential variation in sensitivity among members of the human population (intraspecies).

TABLE 2—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PRALLETHRIN FOR USE IN DIETARY AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS

| | Residential | HECs | HEDs |
|---|---|---|---|
| Residential HECs and HEDs .... | Handler/Outdoor Post-application. | 0.00020 mg/L ..... | 0.006 mg/kg/day. |
| Residential LOC for MOE = 100 (Children <6 years old). | Indoor Post-application without air ventilation. | 0.00014 mg/L ..... | N/A. |
| Residential LOC for MOE = 30 (Children ≥6 years old and Adults). | Indoor Post-application with air ventilation. | Adults: 0.00004 mg/L<br>Children: 0.00003 mg/L. | N/A. |
| | Bystander ..... | 0.00002 mg/L ..... | N/A. |

TABLE 2—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PRALLETHRIN FOR USE IN DIETARY AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS—Continued

| | Residential | HECs | HEDs |
|---|---|---|---|
| Cancer (Oral, dermal, inhalation). | Classification: "Not Likely to be Carcinogenic to Humans." | | |

HEC = human equivalent concentration. HED = human equivalent dose. Kg = kilogram. LOC = level of concern. L = Liter. Mg = milligram. MOE = margin of exposure. N/A = Not applicable.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to prallethrin, EPA considered exposure under the petitioned-for tolerances as well as all existing prallethrin tolerances in 40 CFR 180.545. Acute and chronic aggregate 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).

i. *Acute exposure.* The acute dietary risk assessment is partially refined, and is based on the assumption that as a result of potential use in food handling establishments (FHEs), most commodities will have residues at one-half the limit of quantification (LOQ) of the analytical method used in the FHE residue trials (0.05 ppm). It was also based on the assumptions that all flour food forms will contain residues at the highest level found in the FHE residue trials on flour, and that tree nuts and peanuts will contain residues at the highest level found in the FHE residue trials on peanuts. Based on residue data, the highest residue value (0.0045 ppm) was used for all crops as a result of treatment from the mosquito adulticide use.

The percent FHE value of 4.65% was applied to the FHE residue values, and the adulticide residues were incorporated at a level of 100% (i.e., all foods could potentially have residues resulting from the mosquito adulticide use). Residues from food handling (modified by the % FHE estimate) and mosquito adulticide treatments were combined.

ii. *Chronic exposure.* A chronic dietary risk assessment was not conducted. However, a chronic exposure assessment was conducted to determine background levels of dietary exposure for estimating aggregate risk. The exposure estimates are based on the highest residue value from the FHE residue trials for tree nuts, peanuts, and all flour food forms; and on the LOQ of the method used in the FHE trials (0.10 ppm). The data were treated in the same manner as the data in the acute dietary risk assessment, with the exception that the average residue value from the adulticide trials (0.0007 ppm) was used instead of the highest residue value (0.0045 ppm).

For the chronic exposure assessment, EPA applied a percent FHE value of 4.65% to the FHE residue values and assumed 100 percent crop treated (PCT) for the proposed mosquito adulticide use, just as we have done for the acute exposure assessment. This value is considered to be an overestimate of the potential for the mosquito adulticide to drift onto growing crops. Residues from the FHE and adulticide uses were then combined. Processing factors were not used because the assumption was made that foods in an FHE could be treated after processing.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that prallethrin 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)(F) of FFDCA states that EPA to 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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

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 estimates a maximum 4.65% probability that a food a person consumes contains residues as a result of treatment in an FHE at some point with any pesticide (i.e., it is not specific to prallethrin). This value was derived by taking into account the daily probability of treatment and the percent of expenditures resulting in potential residues in restaurants, commercial kitchens, food warehouses, and food processors. For both the acute and chronic assessments, this value was used for the FHE component of the residue for all commodities with the exception of drinking water.

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 prallethrin may be applied in a particular area.

Specific information on the methodology to estimate PCT can be found in the document entitled ''*Prallethrin: Upper Bound Estimate of the Likelihood of Insecticide Residues on Food Resulting from Treatment in Food Handling Establishments,*'' dated September 7, 2014, by going to *http://www.regulations.gov.*

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for prallethrin. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of prallethrin. 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.*

Based on the First Index Reservoir Screening Tool (FIRST), Tier II Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), and the Pesticide Flooded Application Model (PFAM), the surface water estimated drinking water concentration (EDWC) value of 0.591 parts per billion (ppb) was used in the acute assessment and that the annual average surface water EDWC value of 0.0375 ppb was used in the chronic assessment.

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).

Prallethrin is currently registered for the following uses that could result in residential exposures: A variety of residential pet, indoor and outdoor uses for pests found on turf, and in homes and commercial settings, including food handling establishments. However, for purposes of this assessment, only registered residential products and use sites with the highest application rates or percent active ingredient (a.i.) were assessed because they are representative of the worst case exposure scenarios for the exposed populations.

EPA assessed potential residential handler exposure scenarios resulting from mixing/loading/applying sprays to lawns using hose-end and backpack sprayers because exposure from treating lawns were higher than from other application methods and sites. A quantitative assessment was not required for handling of total release fogger products since the labels state that the room/house must be vacated immediately by the user once initiated.

EPA assessed post-application dermal exposure for adults and children as well as incidental oral (i.e., hand-to-mouth) exposure for children resulting from contact with residues deposited on turf and indoor surfaces following application with aerial and truck-mounted fogger mosquito vector control applications, hand-held spray applications on turf and lawn, and indoor aerosol foggers, respectively. Adult and child post-application inhalation exposure resulting from both aerial and truck-mounted mosquito vector control applications were also assessed. A quantitative post-application inhalation exposure assessment was not performed for turf or indoor aerosol foggers because inhalation exposure from these application methods is anticipated to be negligible. 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 (go to *http://www.regulations.gov* and search under document ID number EPA–HQ–OPP–2008–0489–0006). The members of this group share the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. The cumulative risk assessment for the pyrethroids/pyrethrins was published on November 9, 2011, and is available at *http://www.regulations.gov* under EPA–HQ–OPP–2011–0746. No cumulative risks of concern were identified, allowing the Agency to consider new uses for pyrethroids. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity, and to evaluate the cumulative effects of this class of chemicals, see EPA's Web site at *http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.*

Prallethrin is included in the pyrethroids/pyrethrins cumulative risk assessment. No dietary, residential or aggregate risk estimates of concern have been identified in the single chemical assessment. In the cumulative assessment, residential exposure was the greatest contributor to the total exposure. An existing residential turf use for prallethrin was evaluated to determine the potential contribution it would have on the cumulative risk assessment. Although the turf use was considered the main contributor for residential exposure, the turf assessment indicated that exposure from turf would not impact the residential component of the cumulative risk estimates for the pyrethroids.

Therefore, since the proposed mosquito adulticide contributes far less exposure than the registered turf uses, there will be no impact on the residential component of the cumulative risk estimates.

Dietary exposures make a minor contribution to the total pyrethroid exposure. The dietary exposure assessment performed in support of the pyrethroid cumulative was much more highly refined than that performed for prallethrin. In addition, for the prallethrin risk assessment, the most sensitive apical endpoint in the prallethrin database was selected to derive the POD. Further, the POD selected for prallethrin is specific to prallethrin, whereas the POD selected for the cumulative assessment was based on common mechanism of action data that are appropriate for all 20 pyrethroids included in the cumulative assessment. Dietary exposure to prallethrin residues resulting from the proposed mosquito adulticide use over all crops will contribute very little to the dietary exposure to prallethrin alone; therefore, the proposed use will make an insignificant contribution to dietary risk to the pyrethroids as a whole.

### *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.* The prallethrin toxicity database includes developmental toxicity studies in the rat and rabbit, and a reproduction study in the rat. No evidence of increased qualitative or quantitative susceptibility was noted in any of these studies. This lack of susceptibility is consistent with the results of guideline developmental and reproduction studies with other pyrethroid pesticides.

High-dose studies assessing what dose results in lethality to 50% of the tested population ($LD_{50}$) in the scientific literature indicate that pyrethroid exposure can result in increased quantitative sensitivity in the young, specifically in the form of neurotoxicity. Examination of pharmacokinetic and pharmacodynamic data indicates that the sensitivity observed at high doses is related to pyrethroid age-dependent pharmacokinetics, which is the activity of enzymes associated with the metabolism of pyrethroids. With otherwise equivalent administered doses for adults and juveniles, predictive pharmacokinetic models indicate that the differential adult-juvenile pharmacokinetics will result in a 3x greater dose at the target organ in juveniles compared to adults. No evidence of increased quantitative or qualitative susceptibility was seen in the pyrethroid scientific literature related to pharmacodynamics (the effect of pyrethroids at the target tissue) both with regard to interspecies differences between rats and humans and to differences between juveniles and adults. Specifically, there are *in vitro* pharmacodynamic data and *in vivo* data indicating similar responses between adult and juvenile rats at low doses and data indicating that the rat is a conservative model compared to the human based on species-specific pharmacodynamics of homologous sodium channel isoforms in rats and humans.

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 less than 6 years of age. For the general population, including children greater than 6 years of age, EPA is reducing the FQPA SF to 1x. These decisions are based on the following findings:

i. The toxicology database for prallethrin is considered complete with respect to guideline toxicity studies for prallethrin; however, the Agency lacks additional information to fully characterize the potential for juvenile sensitivity to the neurotoxic effects of pyrethroids. In light of the literature studies indicating a possibility of increased sensitivity in juvenile rats at high doses, EPA identified a need, and requested proposals for, additional non-guideline studies to evaluate the potential for sensitivity in juvenile rats. A group of pyrethroid registrants is currently conducting those studies. Pending the results of those studies, however, the available toxicity studies for prallethrin can be used to characterize toxic effects including potential developmental and reproductive toxicity, as well as neurotoxicity. Acceptable developmental toxicity studies in rats and rabbits, reproduction studies in rats, neurotoxicity studies (acute, subchronic, and developmental) in rats are available. In addition, route-specific dermal and inhalation toxicity studies are available. The Immunotoxicity study has been waived. As discussed in Unit IV.D.2., EPA concludes that the 3x FQPA SF will be adequate for protecting infants and children less than 6 years old.

ii. After reviewing the extensive body of data and peer-reviewed literature on pyrethroids, the Agency has reached a number of conclusions regarding fetal and juvenile sensitivity for pyrethroids, including the following:

- Based on an evaluation of over 70 guideline toxicity studies for 24 pyrethroids submitted to the Agency, including prenatal developmental toxicity studies in rats and rabbits, and pre- and postnatal multi-generation reproduction toxicity studies and DNTs in rats in support of pyrethroid registrations, there is no evidence that pyrethroids directly impact developing fetuses. None of the studies show any indications of fetal toxicity at doses that do not cause maternal toxicity.
- Increased susceptibility was seen in offspring animals in the DNT study with the pyrethroid zeta-cypermethrin (decreased pup body weights) and DNT and reproduction studies with another pyrethroid beta-cyfluthrin (decreased body weights and tremors). However, the reductions in body weight and the other non-specific effects occur at higher doses than neurotoxicity, the effect of concern for pyrethroids. The available developmental and reproduction guideline studies in rats with zeta-cypermethrin did not show increased sensitivity in the young to neurotoxic effects. Overall, findings of increased sensitivity in juvenile animals in pyrethroid studies are rare. Therefore, the residual concern for the postnatal effects is reduced.
- High-dose $LD_{50}$ studies (studies assessing what dose results in lethality to 50% of the tested population) in the scientific literature indicate that pyrethroids can result in increased quantitative sensitivity to juvenile animals. Examination of pharmacokinetic and pharmacodynamic data indicates that the sensitivity observed at high doses is related to pyrethroid age-dependent pharmacokinetics—the activity of enzymes associated with the metabolism of pyrethroids. Furthermore, a rat physiologically-based pharmacokinetic (PBPK) model predicts a 3-fold increase of pyrethroid concentration in juvenile brain compared to adults at high doses.
- *In vitro* pharmacodynamic data and *in vivo* data indicate that adult and juvenile rats have similar responses to pyrethroids at low doses and therefore juvenile sensitivity is not expected at relevant environmental exposures. Further, data also show that the rat is a conservative model compared to the human based on species-specific pharmacodynamics of homologous sodium channel isoforms.

iii. There are no residual uncertainties with regard to dietary exposure. The dietary exposure assessments are based on highly conservative residue levels for the mosquito adulticide use and for the FHE uses. Furthermore, conservative, upper-bound assumptions were used to determine exposure through drinking water and residential sources, such that these exposures have not been underestimated.

Taking all of this information into account, EPA has reduced the FQPA SF for women of child-bearing age because there is no evidence in the over 70 guideline toxicity studies submitted to the Agency that pyrethroids directly impact developing fetuses. In addition, none of the studies show any indications of fetal toxicity at doses that do not cause maternal toxicity. Because there remains some uncertainty as to juvenile sensitivity due to the findings in the high-dose $LD_{50}$ studies, EPA is retaining a 3x FQPA SF for infants and children less than 6 years of age. By age 6, the metabolic system is expected to be at or near adult levels thus reducing concerns for potential age-dependent sensitivity related to pharmacokinetics; therefore for children over 6, a 1x factor

is appropriate. Although EPA is seeking additional data to further characterize the potential neurotoxicity for pyrethroids, EPA has reliable data that show that reducing the FQPA SF to 3x will protect the safety of infants and children less than 6 years old. These data include:

a. Data from developmental and reproductive toxicity guideline studies with prallethrin that show no sensitivity.

b. Data showing that the potential sensitivity at high doses is likely due to pharmacokinetics.

c. A rat PBPK model predicting a 3-fold increase of pyrethroid concentration in the juvenile brain compared to adults at high doses due to age-dependent pharmacokinetics.

d. Data indicating that the rat is a conservative model compared to the human based on species-specific pharmacodynamics of homologous sodium channel isoforms.

iv. Although EPA has required additional data on transferable residues from treated turf for prallethrin, EPA is confident that it has not underestimated turf exposure due to the conservativeness of the default turf transfer value and conservative assumptions in the short-term turf assessment procedures (e.g., assuming residues do not degrade over the thirty day assessment period and assuming high-end activities on turf for every day of the assessment period). The additional data on turf transferable residues have been required in case requirement of exposure assessments is needed on the future, and to further EPA's general understanding of the availability of pesticide residues on turf.

For several reasons, EPA has determined that reliable data show that a 3x factor is protective of the safety of infants and children less than 6 years of age. First, it is likely that the extensive guideline studies with pyrethroids, which indicate that increased sensitivity in juvenile animals in pyrethroid studies is rare, better characterize the potential sensitivity of juvenile animals than the $LD_{50}$ studies. The high doses that produced juvenile sensitivity in the literature studies are well above normal dietary or residential exposure levels of pyrethroids to juveniles and lower levels of exposure anticipated from dietary and residential uses are not expected to overwhelm the juvenile's ability to metabolize pyrethroids, as occurred with the high doses used in the literature studies. The fact that a greater sensitivity to the neurotoxicity of pyrethroids is not found in guideline studies following in utero exposures (based on more than 70 studies for 24 pyrethroids) supports this conclusion, despite the relatively high doses used in the studies. Second, *in vitro* data indicate similar pharmacodynamic response to pyrethroids between juvenile and adult rats. Finally, as indicated, pharmacokinetic modeling only predicts a 3x difference between juveniles and adults. Therefore, the FQPA SF of 3x is protective of potential juvenile sensitivity.

Specific information about the reevaluation of the FQPA SF for pyrethroids may be found in document ID number EPA–HQ–OPP–2011–0746–0011.

### *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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Acute aggregate risk from exposure to prallethrin results from exposure to residues in food and drinking water alone. The acute dietary exposure analysis included both food and drinking water; therefore, acute aggregate risk estimates are equivalent to the acute dietary risk estimates. The acute risk estimate for the general U.S. population is 10% of the aPAD. The population subgroup with the highest acute dietary risk estimate is children 1–2, which uses 76% of the aPAD. Acute aggregate risk is not of concern for the general U.S. population or any other population subgroup.

2. *Chronic risk.* Using the exposure assumptions described in this unit, there is no increase in hazard with increasing dose duration; 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). The short-term aggregate risk assessments resulted in MOEs of 620 for children, and 1,600 for adult females and the general U.S. population. The adult and children's MOEs are greater than their respective LOCs of 100 and 300. As a result, the short-term aggregate risk estimates are not of concern for the general U.S. population or any population subgroup.

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, prallethrin is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the data summarized in Units III.A. and III.C.1.iii., EPA has concluded that prallethrin 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 prallethrin residues.

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

A method based on gas chromatography with electron capture detection (GC/ECD), ID #262, is adequate for the enforcement of tolerances for residues of prallethrin in or on crop commodities. The reported limits of quantitation (LOQs) are 0.01 to 0.10 ppm, depending on the commodity. The limits of detection (LODs) were reported to be 0.004 to 0.06 ppm, depending on the commodity. Multiresidue methods testing for prallethrin have not been conducted, and is not required, based on previous Agency discussions with the petitioner on November 3, 2010.

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 section 408(b)(4) of FFDCA. 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, section 408(b)(4) of FFDCA requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for prallethrin.

## V. Conclusion

Therefore, tolerances are established for residues of the insecticide prallethrin, including its metabolites and degradates, in or on all raw agricultural commodities and processed food from use of prallethrin in food handling establishments where food and food products are held, processed, prepared and/or served, or as a wide-area mosquito adulticide at 1.0 part per million (ppm). Compliance with the tolerance level specified is to be determined by measuring only prallethrin, 2-methyl-4-oxo-3-(2-propyn-1-yl)-2-cyclopenten-1-yl-2,2-dimethyl-3-(2-methyl-1-propen-1-yl)cyclopropanecarboxylate.

EPA is revising 40 CFR 180.545 to clarify the tolerance. EPA is merging paragraphs (a)(1) and (2) together into a new paragraph (a). EPA is removing paragraphs (a)(3) and (4) as they contain language that is more appropriately regulated 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 section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: October 17, 2014.

**Daniel J. Rosenblatt,**

*Acting 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. Revise § 180.545 to read as follows:

### § 180.545 Prallethrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide prallethrin, including its metabolites and degradates, in or on all raw agricultural commodities and processed food from use of prallethrin in food handling establishments where food and food products are held, processed, prepared and/or served, or as a wide-area mosquito adulticide at 1.0 part per million (ppm). Compliance with the tolerance level specified is to be determined by measuring only prallethrin, 2-methyl-4-oxo-3-(2-propyn-1-yl)-2-cyclopenten-1-yl-2,2-dimethyl-3-(2-methyl-1-propen-1-yl)cyclopropanecarboxylate.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2014–25732 Filed 10–28–14; 8:45 am]

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## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## 50 CFR Part 648

**[Docket No. 140822715–4882–02]**

**RIN 0648–BE37**

## Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Tilefish Fishery; 2015–2017 Specifications

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** NMFS issues final specifications for the commercial