TABLE 2—ADDITIONAL REGULATIONS APPROVED FOR WASHINGTON DEPARTMENT OF ECOLOGY (ECOLOGY) DIRECT JURISDICTION

[Applicable in Adams, Asotin, Chelan, Columbia, Douglas, Ferry, Franklin, Garfield, Grant, Kittitas, Klickitat, Lincoln, Okanogan, Pend Oreille, San Juan, Stevens, Walla Walla, and Whitman counties, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction. These regulations also apply statewide for facilities subject to the applicability sections of WAC 173–405–012, WAC 173–410–012, and WAC 173–415–012]

State citation	Title/Subject	State effective date	EPA Approval date	Explanations
Washington Administrative Code, Chapter 173–400—General Regulations for Air Pollution Sources				
*	* * *		*	* *
173–400–131	Issuance of Emission Reduction Credits	4/1/11	11/7/14[Insert **Federal Register** citation].	
173–400–136	Use of Emission Reduction Credits (ERC).	12/29/12	11/7/14[Insert **Federal Register** citation].	
*	* * *		*	* *
173–400–800	Major Stationary Source and Major Modification in a Nonattainment Area.	4/1/11	11/7/14[Insert **Federal Register** citation].	
173–400–810	Major Stationary Source and Major Modification Definitions.	12/29/12	11/7/14[Insert **Federal Register** citation].	
173–400–820	Determining if a New Stationary Source or Modification to a Stationary Source is Subject to these Requirements.	12/29/12	11/7/14[Insert **Federal Register** citation].	
173–400–830	Permitting Requirements	12/29/12	11/7/14[Insert **Federal Register** citation].	
173–400–840	Emission Offset Requirements	12/29/12	11/7/14[Insert **Federal Register** citation].	
173–400–850	Actual Emissions Plantwide Applicability Limitation (PAL).	12/29/12	11/7/14[Insert **Federal Register** citation].	
173–400–860	Public Involvement Procedures	4/1/11	11/7/14[Insert **Federal Register** citation].	

*The EPA's approval of the WAC 173–400–110 through –113, 173–400–036, 173–400–171, and 173–400–560 is not a determination that these regulations meet requirements for a SIP-approved Prevention of Significant Deterioration permitting program (40 CFR 51.166) or a SIP-approved visibility program (40 CFR 51.307) for major sources.

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[FR Doc. 2014–26451 Filed 11–6–14; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0297; FRL–9918–24]

Deltamethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of deltamethrin in or on finfish. Center for Regulatory Services, Inc., on behalf of PHARMAQ AS, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 7, 2014. Objections and requests for hearings must be received on or before January 6, 2015, 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–2014–0297, 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–2014–0297 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 January 6, 2015. 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–2014–0297, 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 May 23, 2014 (79 FR 29729) (FRL–9910–29), 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 3E8178) by the Center for Regulatory Services, Inc, 5200 Wolf Run Shoals Rd., Woodbridge, VA 22192–5755, on behalf of PHARMAQ AS, P.O. Box 267, Skøyen, N–0213 Oslo, Norway. The petition requested that 40 CFR 180.435 be amended by establishing tolerances for residues of the insecticide deltamethrin, (1R, 3R)-3(2,2-dibromovinyl)-2,2-dimethylcyclopropane-carboxylic acid (*S*)-alpha-cyano-3-phenoxybenzyl ester and its major metabolites: Trans-deltamethrin, (*s*)-alpha-cyano-3-phenoxybenzyl-(1R, 3S)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate, and alpha-*R*-deltamethrin, (*R*)-alphacyano-3-phenoxybenzyl-(1R, 3R)-3-(2,2-dibromovinyl)-2,2-dimethyl cyclopropanecarboxylate, in or on finfish at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by PHARMAQ AS, the registrant, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the petition by correcting the commodity definition. The Agency also revised the tolerance expression for deltamethrin. The reasons for these changes are explained in Unit IV.D.

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 2 to 5 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. The Wolansky et al. acute oral study (2006), 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). The study endpoint and dose were used for all exposure scenarios.

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 Food Quality Protection Act Safety Factor (FQPA SF) will be 1× for adults and children >6 years old, and 3× 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, PD 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 1×.

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 BMD analysis using one standard deviation from the control group as the BMR as suggested for continuous endpoints in the Agency's BMD guidance (EPA, 2012). The Wolansky et al. 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 the document entitled ''Deltamethrin. Human Health Risk Assessment for the Proposed Use of Deltamethrin without U.S. Registration on Finfish'' at p. 46 in docket ID number EPA–HQ–OPP–2014–0297.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological PODs and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for deltamethrin used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DELTAMETHRIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (≥6 years old)	POD = Wolansky ..... $BMDL_{1SD}$ = 1.49 mg/kg UF_A = 10 x UF_H = 10 x FQPA SF = 1 x	Acute RfD = 0.015 mg/kg aPAD = 0.015 mg/kg/day	Wolansky $BMDL_{1SD}$ = 2.48 mg/kg based on decreased motor activity.
Acute dietary (<6 years old)	POD = Wolansky ..... $BMDL_{1SD}$ = 1.49 mg/kg UF_A = 10 x UF_H = 10 x FQPA SF = 3 x	Acute RfD = 0.015 mg/kg aPAD = 0.005 mg/kg/day	Wolansky $BMDL_{1SD}$ = 2.48 mg/kg based on decreased motor activity.
Chronic Dietary	A chronic dietary risk assessment was not conducted because there is no apparent increase in hazard from repeated/chronic exposures to deltamethrin.		
Incidental oral short-term (1 to 30 days).	POD = Wolansky ..... $BMDL_{1SD}$ = 1.49 mg/kg UF_A = 10 x UF_H = 10 x FQPA SF = 3 x	LOC for MOE = 300	Wolansky $BMDL_{1SD}$ = 2.48 mg/kg based on decreased motor activity.
* Inhalation short-term (1 to 30 days; ≥6 years old).	POD = Wolansky ..... $BMDL_{1SD}$ = 1.49 mg/kg UF_A = 10 x UF_H = 10 x FQPA SF = 1 x	LOC for MOE = 100	Wolansky $BMDL_{1SD}$ = 2.48 mg/kg based on decreased motor activity.
* Inhalation short-term (1 to 30 days; <6 years old).	POD = Wolansky ..... $BMDL_{1SD}$ = 1.49 mg/kg UF_A = 10 x UF_H = 10 x FQPA SF = 3 x	LOC for MOE = 300	Wolansky $BMDL_{1SD}$ = 2.48 mg/kg based on decreased motor activity.
Cancer (oral, dermal, inhalation).	Classification: ''Not likely to be Carcinogenic to Humans'' based on the absence of treatment related tumors in two adequate rodent carcinogenicity studies.		

$BMDL_{1SD}$ = the 95% lower confidence limit of the central estimate of the dose that results in decreased motor activity compared to control animals based upon one standard deviation using Benchmark Dose Analysis. FQPA SF = Food Quality Protection Act Safety Factor. LOC = level of concern. Mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. PAD = population adjusted dose (a = acute, c = chronic). POD = Point of departure: 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).

* Inhalation toxicity is assumed to be equivalent to toxicity via the oral route.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to deltamethrin, EPA considered exposure under the petitioned-for tolerances as well as all existing deltamethrin tolerances in 40 CFR 180.435. EPA assessed dietary exposures from deltamethrin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for deltamethrin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance level residues for most commodities and Pesticide Data Program (PDP) monitoring data for apples, apple juice, apple sauce, cantaloupe, carrots, cereal grains, cucumbers, milk, pears, soybeans, tomatoes, and watermelons. Maximum percent crop treated (PCT) estimates were used for some commodities. Default processing factors were used for some processed commodities and empirical factors were used for others.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, since deltamethrin is registered for use in food handling establishments (FHEs), residue values were entered for all commodities in the Dietary Exposure Evaluation Model software-Food Commodity Intake Database (DEEM–

FCID). Tolerance level residues were used for most commodities. For cereal grain commodities, average monitoring data values were used. For milk, PDP monitoring data were used. For the commodities for which the only established tolerance is the FHE tolerance, a residue value of 0.025 ppm (½ the FHE tolerance) was used. The FHE tolerance is based on the Limit of Quantitation (LOQ), and ½ the tolerance was used as a refinement in the dietary assessment. For commodities with tolerances for agricultural uses, average PCT estimates were generally used. For the commodities for which ½ 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.

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 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; 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% for the commodities for which ½ the FHE tolerance was used; 5% for canola and peppers; 40% for globe artichokes; and 100% for all other commodities for which direct treatment is allowed.

In the chronic assessment, for the commodities for which ½ 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.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (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.*

Based on the Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of deltamethrin for acute and chronic exposures are estimated to be 0.200 parts per billion (ppb) for both surface water and ground water. 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. EPA assessed potential exposures for residential handlers using several application methods including handwand and backpack sprayers to treat lawns, turf, and trees; and using shaker cans and aerosol sprays for trees and indoor crack and crevice applications. 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 were not quantitatively assessed since no dermal hazard was identified for deltamethrin and inhalation exposures are typically negligible in outdoor settings. Furthermore, the inhalation exposure assessment performed for residential handlers is representative of worse case inhalation exposures and is considered protective for post-application inhalation scenarios.

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 in the **Federal Register** of November 9, 2011 (76 FR 69726) (FRL–8888–9), 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 import tolerance on finfish 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 proposed import tolerance for finfish 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 (10×) 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 SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF 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 POD, 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 3× for infants and children <6 years old; and to 1× 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 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 PD and PK 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 DNT or 2-generation reproduction study and, therefore, there is no susceptibility at these doses. The Agency has retained a 3× uncertainty factor to protect for exposures of

children <6 years of age based on increased quantitative susceptibility seen in studies on pyrethroid PK (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 prenatal 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 PD.

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 80% of the aPAD for children 3–5 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 530 for children 1–2 years old, the population group receiving the greatest exposure. Because EPA's level of concern for deltamethrin is a 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.

Multi-residue methods data for *cis*-deltamethrin and *trans*-deltamethrin were previously sent to the Food and Drug Administration (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.

The Codex has not established a MRL for deltamethrin in finfish.

C. Response to Comments

One comment was received from the general public urging the Agency to tighten regulations for pesticides tolerances and uses. The commenter particularly addressed carcinogenic chemicals and their effects on children's health.

The toxicological database for deltamethrin shows that the chemical does not pose a cancer risk to humans. Deltamethrin is classified as ''Not likely to be carcinogenic to humans'' based on the absence of treatment related tumors in adequate rodent studies. 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, PODs, and uncertainty factors that are protective for all populations, including infants and children, and that have a strong scientific foundation. In addition, there are ongoing efforts to develop data to gain more information concerning the potential sensitivity of infants and young children to pyrethroids as a class. EPA has addressed the variability of sensitivities of the population to deltamethrin, including infants and children in Unit III.D.

D. Revisions to Petitioned-For Tolerances

Pharmaq AS requested the establishment of a permanent tolerance, for residues of the insecticide deltamethrin in all imported commercially farmed finfish at 0.01 ppm. Since there is no commodity definition covering all finfish, the Agency is establishing tolerances of 0.01 ppm in ''fish—freshwater finfish,'' ''fish—freshwater finfish, farm raised,'' ''fish—saltwater finfish, other,'' and ''fish—saltwater finfish, tuna.''

The Agency is revising the tolerance expression to clarify that:

1. As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of deltamethrin not specifically mentioned.

2. Compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of deltamethrin, including its metabolites and degradates in or on fish—freshwater finfish; fish—freshwater finfish, farm raised; fish—saltwater finfish, other; and fish—saltwater finfish, tuna at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 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 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 29, 2014.

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:

■ a. Revise the introductory text of paragraph (a)(1).

■ b. Add alphabetically to the table in paragraph (a)(1) the following commodities.

The amendments read as follows:

§ 180.435 Deltamethrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of deltamethrin, including its metabolites and degradates, in or on the commodities listed in the following table. 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.

Commodity	Parts per million
* * * * *	
Fish—freshwater finfish	0.01
Fish—freshwater finfish, farm raised	0.01
Fish—saltwater finfish, other	0.01
Fish—saltwater finfish, tuna	0.01
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