(not included are all other types of silviculture facilities);

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0472; FRL–9371–7]

Zeta Cypermethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of zeta-cypermethrin in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 7, 2012. Objections and requests for hearings must be received on or before February 5, 2013, 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–2010–0472, 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), EPA West 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: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; email address: *ertman.andrew@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–2010–0472 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 February 5, 2013. 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–2010–0472, 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** issue of August 4, 2010 (75 FR 46924) (FRL–8834–9), 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 0E7717) by the IR–4 Project, Rutgers, The State University of New Jersey, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.418 be amended by establishing tolerances for residues of the insecticide zeta-cypermethrin, in or on pistachio at 0.05 parts per million (ppm), artichoke, globe at 0.80 ppm; barley, grain at 1.7 ppm; barley, hay at 5.0 ppm; barley, straw at 19.0 ppm; buckwheat, grain at 1.7 ppm; buckwheat, hay at 5.0 ppm; buckwheat, straw at 19.0 ppm; oat, grain at 1.7 ppm; oat, hay at 5.0 ppm; oat, straw at 19.0 ppm; rye, grain at 1.7 ppm; rye, hay at 5.0 ppm; and rye, straw at 19.0 ppm. That document referenced a summary of the petition prepared by FMC, the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

In the **Federal Register** issue of February 25, 2011 (76 FR 10584) (FRL–8863–3), 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 0E7804) by the IR–4 Project, Rutgers, The State University of New Jersey, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.418 be amended by establishing tolerances for residues of the insecticide zeta-cypermethrin, (*S*-cyano(3-phenoxyphenyl) methyl (±))(cis-trans 3-(2,2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate and

its inactive *R*-isomers, in or on avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple at 0.45 ppm. That document referenced a summary of the petition prepared by FMC, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions, EPA has modified the levels for which tolerances are being established for some commodities. The reason for these changes is 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 zeta-cypermethrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with zeta-cypermethrin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The petitions for registration of these new uses of zeta-cypermethrin rely on zeta-cypermethrin data, as well as previously submitted data for the related registered insecticide cypermethrin, and the pending new active ingredient alpha-cypermethrin. Alpha-cypermethrin, cypermethrin, and zeta-cypermethrin are all pyrethroid insecticides and are isomer mixtures of the same chemical. Cypermethrin consists of a mixture of eight isomers (four diastereoisomeric pairs). Zeta-cypermethrin is composed of four of the eight isomers of cypermethrin, and also contains one of the isomers in alpha-cypermethrin. Alpha-cypermethrin consists of two of the four cis-isomers of cypermethrin.

Alpha-cypermethrin, cypermethrin, and zeta-cypermethrin have been evaluated for a variety of toxic effects in experimental toxicity studies. Behavioral changes commonly seen with type II pyrethroids were consistently noted in the toxicology database. These included tremors, gait abnormalities, limb conditions, ataxia, and hypersensitivity. Additionally, body weight changes were routinely observed and mortality was seen in a few studies in rats and dogs. Clinical signs were also noted in all acute neurotoxicity studies. Decreased activity, gait abnormalities, tremors, limb conditions, and hypersensitivity were observed at the mid and high doses. Additionally, slight nerve degeneration was seen in the acute neurotoxicity study with alpha-cypermethrin at the high dose. In the subchronic neurotoxicity studies with cypermethrin and zeta-cypermethrin, similar behavioral effects were seen along with decreased food consumption, body weight, and body weight gain.

Dermal toxicity studies are available for zeta-cypermethrin (rat) and cypermethrin (rabbit), in which local irritation was observed in rats and rabbits at the highest doses tested. No systemic effects were observed in the 21-day dermal study in the rat conducted with zeta-cypermethrin at dose levels up to 1,000 milligram/kilogram/day (mg/kg/day). In the dermal toxicity study in rabbits with cypermethrin, systemic effects were observed (focal necrosis of the liver, decreased testicular weights, and decreased body weight in females). However, these observations in the rabbit were not used for risk assessment because the testing method (i.e., abraded skin) does not simulate actual exposure and results in compromised test conditions. Additionally, there would be physiological differences between abraded and non-abraded animals, further undermining the relevance of these results for risk assessment.

Developmental toxicity and reproduction studies are available for the cypermethrins. In the developmental toxicity studies in rats with cypermethrin and zeta-cypermethrin, there was no evidence of developmental toxicity up to the highest doses tested. Maternal toxicity included decreased body weight gain and food consumption in both chemicals. Splayed limbs, spasms, and hypersensitivity to noise and convulsions were seen with cypermethrin, and ataxia, urine-stained abdominal fur, and fecal-stained fur were seen with zeta-cypermethrin. In the developmental toxicity study in rats with alpha-cypermethrin, offspring effects were limited to decreased fetal body weight. Maternal effects observed in the study were unsteady gait, piloerection, limb splay, and hypersensitivity to sound and touch at the same dose. In the developmental toxicity studies in rabbits with alpha-cypermethrin, cypermethrin, and zeta-cypermethrin, there was no evidence of developmental toxicity up to the highest dose tested. Maternal effects seen with cypermethrin included decreased body weight gain, anorexia, abdomino-genital staining, decreased feces, and red or pink material in the pan. With alpha-cypermethrin, maternal effects were body weight loss and decreased food consumption. Multi-generation reproduction studies in rats are available for cypermethrin and zeta-cypermethrin. In the reproduction study with cypermethrin, decreased body weight gain was observed in adult animals and decreased body weight was seen in offspring animals at the highest dose tested. In the reproduction study with zeta-cypermethrin, decreased body weight gain and mortality were observed in offspring animals in the presence of mortality, increased brain weights, decreased body weights, and neurotoxicity in maternal animals.

No effects were observed in an immunotoxicity study in rats with alpha-cypermethrin up to the limit dose.

Cypermethrin is classified as a Group C ''Possible human carcinogen,'' based on an increased incidence of lung adenomas and adenomas plus carcinomas combined in females in a mouse carcinogenicity study. The presence of common benign tumors (lung adenomas), in one species (mice) and one sex (female), with no increase in the proportion of malignant tumors or decrease in the time-to-tumor occurrence, together with the lack of

mutagenic activity, was not considered strong enough to warrant a linear or no-threshold approach to quantitation of human cancer risk. Quantification of risk using a non-linear approach (i.e., acute population adjusted dose (aPAD), acute reference dose (aRfD)) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to cypermethrin. While the Agency would typically use a chronic population adjusted dose (cPAD) to protect for cancer concerns, use of the aPAD is protective because increasing toxicity with increasing duration of exposure is not demonstrated for the cypermethrins. The no-observed-adverse-effect-level (NOAEL) observed in the mouse cancer study in which tumors were observed is 14 mg/kg/day, 2-fold higher than the point of departure (POD) used for acute risk assessment. The lowest-observed-adverse-effect-level (LOAEL) in the mouse cancer study is 57 mg/kg/day based on liver effects, not tumor formation. The tumors were seen at 229 mg/kg/day. The acute POD of 7.16 mg/kg/day selected for risk assessment is 32-fold lower than the dose that induced lung tumors in mice. Only the mouse study with cypermethrin resulted in tumor formation, no evidence of carcinogenicity was observed in cancer studies in rats with cypermethrin or mice with alpha-cypermethrin.

Acute lethality studies conducted with alpha-cypermethrin, cypermethrin, and zeta-cypermethrin indicate moderate acute toxicity via the oral route and low toxicity via the acute dermal or inhalation routes. Additionally, mild irritation was seen in primary eye and skin irritation studies but no dermal sensitization was observed.

Specific information on the studies received and the nature of the adverse effects caused by zeta-cypermethrin as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* on pp. 60–67 of the document entitled ''Zeta-Cypermethrin—Human Health Risk Assessment for New Poultry House Use and Agricultural Uses on Tropical Fruit, Artichoke, Barley, Oat, Rye, Buckwheat, and Pistachio'' in docket ID number EPA–HQ–OPP–2010–0472.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological PODs and levels of concern (LOCs) 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. The 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 zeta-cypermethrin used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ZETA-CYPERMETHRIN 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 (children ≥ 6 years old and adults).	Wolansky $BMDL_{1SD}$ = 7.16 mg/kg. UF_A = 10x UF_H =10x FQPA SF = 1x	Acute RfD = 0.07 mg/kg/day. aPAD = 0.07 mg/kg/day	Wolansky BMD = 11.20 mg/kg based on motor activity.
Acute dietary (children <6 years old)	Wolansky $BMDL_{1SD}$ = 7.16 mg/kg. UF_A = 10x UF_H =10x FQPA SF = 3x	Acute RfD = 0.07 mg/kg/day. aPAD = 0.023 mg/kg/day	Wolansky BMD = 11.20 mg/kg based on motor activity.
Chronic dietary (All populations)	Because of the rapid reversibility of the most sensitive neurotoxicity endpoint used for quantifying risks, there is no increase in hazard with increasing dosing duration, and therefore the acute dietary endpoint is protective for chronic exposure		
Incidental oral short-term (1 to 30 days) ...	Wolansky $BMDL_{1SD}$ = 7.16 mg/kg. UF_A = 10x UF_H =10x FQPA SF = 3x	LOC for MOE = 300	Wolansky BMD = 11.20 mg/kg based on motor activity.
Inhalation short-term (1 to 30 days) (children <6 years old).	NOAEL = 0.01 mg/L ..... HEC = 0.008 mg/L HED = 1.15 mg/kg/day UF_A = 3x UF_H = 10x FQPA SF = 3x	LOC for MOE = 100	21-Day inhalation study in the rat. LOAEL = 0.05 mg/L based on increased salivation.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ZETA-CYPERMETHRIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Inhalation short-term (1 to 30 days) (children ≥ 6 years old and adults).	NOAEL = 0.01 mg/L HEC = 0.008 mg/L HED = 1.15 mg/kg/day UF_A = 3x UF_H = 10x FQPA SF = 1x	LOC for MOE = 30	21-Day inhalation study in the rat. LOAEL = 0.05 mg/L based on increased salivation.
Cancer (oral, dermal, inhalation)	Zeta-cypermethrin has been classified as a possible human carcinogen. Because of the rapid reversibility of the most sensitive neurotoxicity endpoint used for quantifying risks, there is no increase in hazard with increasing dosing duration. Therefore, the acute dietary endpoint is protective of the endpoints from repeat dosing studies, including cancer dietary exposures.		

1SD = 1 standard deviation. BMD = benchmark dose. BMDL = benchmark dose (lower limit of a 95% confidence interval). FQPA SF = Food Quality Protection Act Safety Factor. HEC = human equivalent concentration. HED = human equivalent dose. L = Liter. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute). 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).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to zeta-cypermethrin, EPA considered exposure under the petitioned-for tolerances as well as all existing zeta-cypermethrin tolerances in 40 CFR 180.418. EPA assessed dietary exposures from zeta-cypermethrin 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 zeta-cypermethrin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted a partially refined (probabilistic) dietary exposure assessment to determine the exposure and risk estimates which result from all the existing uses of cypermethrin and zeta-cypermethrin, as well as proposed new uses of alpha-cypermethrin and zeta-cypermethrin. Anticipated residues from USDA Pesticide Data Program (PDP) monitoring data, field trial data, and empirical processing factors were used where appropriate. Percent crop treated (PCT) estimates were used for some commodities.

ii. *Chronic exposure.* Based on the data summarized in Unit III.A., there is no increase in hazard from repeated exposures to zeta-cypermethrin; the acute dietary exposure assessment is protective for chronic dietary exposures because acute exposure levels are higher than chronic exposure levels. Accordingly, a dietary exposure assessment for the purpose of assessing chronic dietary risk was not conducted.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or non-linear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier non-cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. As noted in Unit III.A., the Agency has determined that quantification of risk using a non-linear approach (i.e., aPAD) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to zeta-cypermethrin. Additionally, because an assessment of cancer risk would estimate exposure based on average residue levels and the acute assessment used high-end residue levels, the acute dietary assessment will be protective of any cancer effects resulting from consumption of zeta-cypermethrin residues in foods.

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

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

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

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

The following maximum PCT estimates were used in the acute dietary risk assessment for the following crops that are currently registered for zeta-cypermethrin/cypermethrin: Almonds, 2.5%; apples, 2.5%; broccoli, 30%; cabbage, 30%; carrot, 10%; cauliflower, 25%; celery, 60%; cherries, 5%; grapefruit, 50%; green beans, 20%; green peas, 15%; lemon, 2.5%; lettuce, 65%; orange, 45%; peach, 5%; peppers,

30%; potato, 5%; spinach, 45%; sweet corn, 20%; tomato, 10%; and watermelon, 10%.

The following average PCT estimates were used to calculate average dietary exposures in order to assess short-term aggregate risk to the cypermethrins for the following crops that are currently registered for cypermethrin/zeta-cypermethrin: Almonds, 1%; apples, 1%; broccoli, 20%; cabbage, 15%; carrot, 2.5%; cauliflower, 15%; celery, 35%; cherries, 5%; grapefruit, 35%; green beans, 15%; green peas, 10%; lemon, 1%; lettuce, 55%; orange, 35%; peach, 2.5%; peppers, 15%; potato, 1%; spinach, 30%; sweet corn, 15%; tomato, 5%; and watermelon, 2.5%.

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

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which zeta-cypermethrin 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 zeta-cypermethrin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of zeta-cypermethrin. 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) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of zeta-cypermethrin for acute exposures are estimated to be 3.77 parts per billion (ppb) for surface water and 0.0036 ppb for ground water. The annual average typically used for chronic exposures are estimated to be 0.066 ppb for surface water and 0.0036 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 3.77 ppb was used to assess the contribution to drinking water. For the purpose of assessing short-term aggregate risk (i.e., food, drinking water, and residential exposures) the chronic water concentration value of 0.066 ppb was used to assess the contribution to drinking water.

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). Cypermethrin and zeta-cypermethrin are registered for use on a variety of indoor and outdoor residential environments including: Lawns, gardens, pets, and indoor surfaces and spaces.

EPA assessed residential exposure using the following assumptions: The quantitative exposure/risk assessment developed for residential handlers is based on the following scenarios:

- Mixer/loader/applicator using hose-end sprayer on turf.
- Mixer/loader/applicator using backpack on turf and gardens.
- Mixer/loader/applicator using manually pressurized handwand for indoor surfaces.
- Application via aerosol can for indoor surfaces and space.

Since a dermal endpoint was not identified, only a quantitative inhalation handler exposure assessment was performed. Residential handler inhalation exposure estimates were calculated based on a human equivalent concentration and human equivalent dose which reflect 24 hours of exposure. Since handler exposure is expected to be significantly less than 24 hours, the inhalation exposure estimates are sufficiently protective of all scenarios (turf, gardens, and indoor surface space). Although there is potential inhalation exposure resulting from the application of dog tags and spot-on products for pets, inhalation exposure is considered negligible for these scenarios and therefore a quantitative assessment was not performed for these uses.

There is the potential for post-application exposure for individuals as a result of being in an environment that has been previously treated with cypermethrin or zeta-cypermethrin. Post-application inhalation exposure resulting from activities on or around previously treated turf is generally not assessed; the combination of low vapor pressure for chemicals typically used as active ingredients in outdoor residential pesticide products and dilution in outdoor air is likely to result in minimal inhalation exposure. Therefore, a quantitative post-application inhalation exposure assessment for cypermethrin turf uses was not conducted. Since a dermal endpoint was not identified, and indoor post-application inhalation exposure resulting from aerosol space sprays, foggers, and pet (i.e., dog tag, spot-on) uses is negligible, the only potential post-application exposure pathways of concern are incidental oral for children, and post-application inhalation exposure for adults and children resulting from indoor crack and crevice applications made with a manually pressurized handwand. The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenarios:

- Incidental oral (hand-to-mouth, object-to-mouth, and soil ingestion) exposure from turf for children.
- Incidental oral (hand-to-mouth and object-to-mouth) exposure from indoor foggers for children.
- Incidental oral (hand-to-mouth and object-to-mouth) exposure from pets for children.

• Inhalation exposure for adults and children resulting from crack and crevice application to an indoor surface.

• Incidental oral (hand-to-mouth and object-to-mouth) exposure for children from indoor surface applications.

Risk estimates resulting from different exposure routes may be combined when it is likely that they can occur simultaneously based on the use pattern and when the toxicological effects across different routes of exposure are the same. Although, in the case of children, inhalation and incidental oral exposure routes share a common toxicological endpoint, risk estimates were not combined for those routes for turf, indoor fogger, and pet since post-application inhalation exposure is considered negligible. However, inhalation and incidental oral exposures were combined for post-application risk assessment associated with the indoor crack and crevice use. Inhalation and incidental oral routes have different LOCs. Therefore, in order to combine exposure from the various routes the aggregate risk index (ARI) approach is used to estimate exposure and risk. When this approach is used, aggregate risks are not of concern provided the calculated ARI is greater than one.

The incidental oral scenarios from indoor exposure following crack and crevice applications and outdoor exposure from turf were not combined, not only because they are not likely to co-occur, but also because combining these scenarios would be overly conservative due to the conservative nature of each of the individual assessments.

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 is required to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. The Agency has determined that the pyrethroids and pyrethrins, including zeta-cypermethrin, share a common mechanism of toxicity. 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 in the **Federal Register** issue of November 9, 2011 (76 FR 69726) (FRL–8888–9), and is available at *http://www.regulations.gov* in the docket, EPA–HQ–OPP–2011–0746. Further information about the determination that pyrethroids and pyrethrins share a common mechanism of toxicity may be found in document ID number EPA–HQ–OPP–2008–0489–0006.

The cypermethrins were included in a recent cumulative risk assessment for pyrethrins and pyrethroids. The proposed new uses of zeta-cypermethrin will not significantly impact the cumulative assessment because, in the cumulative assessment, residential exposure was the greatest contributor to the total exposure. As there are no new residential uses for the cypermethrins, the proposed new uses will have no impact on the residential component of the cumulative risk estimates.

Dietary exposures make a minor contribution to total pyrethroid exposure. The dietary exposure assessment performed in support of the pyrethroid cumulative was much more highly refined than that performed for the single chemical. The dietary exposure assessment for the single chemical included conservative assumptions, using field trial data for many commodities, including the proposed new uses with the assumption of 100 PCT, and the most sensitive apical endpoint in the cypermethrins hazard database was selected to derive the POD. Additionally, the POD selected for zeta-cypermethrin is specific to the cypermethrins, 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.

For information regarding EPA's efforts to evaluate the risk of exposure to pyrethroids, 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 10-fold (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.* In guideline developmental and reproduction studies with the cypermethrins, there was no evidence of increased qualitative or quantitative susceptibility in rats or rabbits.

In a guideline Developmental Neurotoxicity (DNT) study with zeta-cypermethrin, there was increased sensitivity in the offspring based on body weight changes in pups (5–10%) in the absence of treatment-related effects in maternal animals. Although, there was a 5–8% decrease in maternal body weight in this study, a body weight decrease of <10% is generally not considered adverse in adults, as this is considered to be within the range of variability because the magnitude of body weight *per* se is typically small (as an example, a 3 gram (g) decrease in body weight from a 338 g rat), and adults are no longer in the growth/development phase. In contrast, the offspring are at a stage of growth and development and are therefore expected to be gaining rather than losing weight. Thus, a smaller percent decrease in body weight is considered adverse in the young relative to adults. In the case of zeta-cypermethrin, the decrease in body weight of the young is comparable to adults; however, it was considered adverse in the young but not in the adults. This disparity in interpretation leads to an apparent increase in sensitivity in the young; however, concern is reduced since the magnitude of body weight decrements was similar in adult and young animals. The results from the DNT study are very similar to results observed in the reproduction studies where body weight changes (decreased body weight gain) were seen in maternal and offspring animals at doses similar to those in the DNT study, with no indication of increased susceptibility. Therefore, there is no residual concern for effects observed in the study. Additionally, there are well characterized dose responses with clear NOAELs and LOAELs for effects seen in the DNT and reproduction studies and the endpoints and PODs selected for risk assessment are protective.

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 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—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 inter-species 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 is reducing the FQPA SF 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. The decisions regarding the FQPA SFs being used are based on the following considerations:

i. The toxicology database for the cypermethrins is not complete. While the database is considered to be complete with respect to the guideline toxicity studies for zeta-cypermethrin, EPA lacks additional data to fully characterize the potential for juvenile sensitivity to neurotoxic effects of pyrethroids. In light of the literature studies indicating a possibility of increased sensitivity in juvenile rats at high doses, EPA has requested proposals for study protocols which could identify and quantify potential juvenile sensitivity. However, when evaluated together, the toxicity studies for alpha-cypermethrin, cypermethrin, and zeta-cypermethrin can be used to characterize toxic effects including potential developmental and reproductive toxicity, immunotoxicity, and neurotoxicity. Acceptable developmental toxicity studies in rats and rabbits, reproduction studies in rats, neurotoxicity studies (Acute Neurotoxicity (ACN), Subchronic Neurotoxicity (SCN), and DNT) in rats, and immunotoxicity studies in rats are available. In addition, route-specific dermal and inhalation studies are available.

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 zeta-cypermethrin (decreased pup body weights) and DNT and reproduction studies with 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 three-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 and residential exposure. The dietary exposure assessments are based on high-end health protective residue levels (that account for parent and metabolites of concern), processing factors, and PCT 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.

Taking all of this information into account, EPA has reduced the FQPA SF for women of child-bearing age and children over 6 to 1X because there is no evidence in the over 70 guideline toxicity studies submitted to the Agency, including prenatal developmental toxicity studies in rats and rabbits, and multi-generation reproduction toxicity studies and DNTs in rats, that pyrethroids directly impact developing fetuses. Additionally, 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 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-dependant sensitivity related to pharmacokinetics. EPA is seeking additional data to further characterize the potential neurotoxicity for pyrethroids. However, EPA has reliable data that show that reducing the FQPA SF to 3X will protect the safety of infants and children. These data include:

- Data from guideline studies with zeta-cypermethrin at relatively high doses that show no sensitivity with regard to neurotoxic effects (the most sensitive effect for the pyrethroids) and no residual concern regarding overall juvenile sensitivity (i.e., sensitivity seen in body weight changes occurred at doses above the level chosen for the POD).
- Data showing that the potential sensitivity at high doses is likely due to pharmacokinetics.
- A rat PBPK model predicting a three-fold increase of pyrethroid concentration in juvenile brain compared to adults at high doses due to age-dependent pharmacokinetics.
- Data indicating that the rat is a conservative model compared to the human based on species-specific pharmacodynamics of homologous sodium channel isoforms.

For several reasons, EPA concludes these data show that a 3X factor is protective of the safety of infants and children. First, it is likely that the extensive guideline studies with zeta-cypermethrin showing no neurotoxicity sensitivity between adults and juveniles 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 76 studies for 24 pyrethroids) supports this conclusion, despite the relatively high doses used in the studies. Second, *in vitro* and *in vivo* 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.

The portion of the uncertainty factor that accounts for potential pharmacodynamic differences between animals and rats (i.e., the inter-species extrapolation factor) are likely to overstate the risk of zeta-cypermethrin given the data showing similarities in pharmacodynamics between animals and humans. For the inter-species factor, the pharmacodynamic portion of the factor is generally considered to be 3X, however for pyrethroids the actual difference is likely to be lower than 3X. In addition, there are data that show that there are no lifestage pharmacodynamic differences between young and adult rats. Standard uncertainty factors, such as those used in the zeta-cypermethrin risk assessment, assume that there will be such differences. Finally, as indicated, pharmacokinetic modeling only predicts a 3X difference between juveniles and adults. Thus, even if there is increased juvenile neurotoxic sensitivity and even if the existing inter-species factor does not provide extra protection due to the conservative nature of their pharmacodynamic components for pyrethroids, the 3X additional factor will protect the young.

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 aPAD and 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 alpha-cypermethrin, cypermethrin, and zeta-cypermethrin will occupy 87% of the aPAD for all infants less than 1 year old and children 1–2 years old, the population groups receiving the greatest exposure.

2. *Chronic risk.* Based on the data summarized in Unit III.A., there is no increase in hazard with increasing dosing duration. Furthermore, chronic dietary exposures will be lower than acute exposures. Therefore, the acute aggregate assessment is protective of potential chronic aggregate exposures.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Cypermethrin and zeta-cypermethrin are 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 cypermethrin and zeta-cypermethrin.

For assessing short-term aggregate risk, the average dietary exposure estimate was used since it represents a background exposure level from food and drinking water that may co-occur with residential exposures. Dietary, inhalation, and incidental oral (hand to mouth) risks for children, and dietary and inhalation risks for adults were combined in this assessment, since the toxicological endpoints were the same. However, the LOC values for children younger than 6 years old were different for oral and inhalation exposure, with an incidental oral LOC of 300, and an inhalation LOC of 100. Likewise, the inhalation and dietary LOCs for adults were different, with an inhalation LOC of 30 and a dietary LOC of 100. Therefore, the respective risk estimates are combined using the ARI approach. When this approach is used, aggregate risks are not of concern provided the calculated ARI is greater than 1. The ARI for adults was calculated to be 56 and the ARI for children was 2.3. Because these ARIs are greater than 1, the risk estimates are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term aggregate risk assessment was not conducted because zeta-cypermethrin is acutely toxic and does not increase in potency with repeated dosing. Because the neurotoxicity POD used for acute risk assessment is lower (more protective) than PODs for longer durations of exposure and acute and short-term exposure levels are higher than longer term exposure levels, the acute and short-term aggregate assessments are protective for intermediate-term aggregate risks anticipated from cypermethrin and zeta-cypermethrin exposure.

5. *Aggregate cancer risk for U.S. population.* For the reasons discussed in Unit III.A. (cancer effects are non-linear and appear at higher doses than acute effects) and Unit III.E.2. (chronic exposures are lower than acute exposures), the acute aggregate assessment is protective of potential cancer risk.

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 alpha-cypermethrin, cypermethrin, and zeta-cypermethrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate tolerance-enforcement methods are available in ''PAM Volume II'' for determining residues of alpha-cypermethrin, cypermethrin, and zeta-cypermethrin in plant (Method I) and livestock (Method II) commodities. Both methods are gas chromatographic methods with electron-capture detection (GC/ECD), and have undergone successful Agency petition method validations (PMVs). Method I has a limit of detection (LOD) of 0.01 ppm, and Method II has LODs of 0.005 ppm in milk, and 0.01 ppm in livestock tissues. These methods are not stereospecific; thus no distinction is made between residues of cypermethrin (all 8 stereoisomers), zeta-cypermethrin

(enriched in 4 isomers) and alpha-cypermethrin (2 isomers).

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.

There are multiple Codex MRLs for zeta-cypermethrin, but all are in conjunction with MRLs for total cypermethrin isomers (no MRLs have been established solely for zeta-cypermethrin). However, although the definitions of the covered isomers in the Codex MRLs and U.S. tolerances differ formally, they are effectively harmonized since the tolerance enforcement methods are not stereo-specific, and thus do not distinguish between residues of alpha-cypermethrin, cypermethrin, and zeta-cypermethrin. For enforcement purposes, the same moiety is being regulated. These tolerances will result in harmonized MRLs between EPA and Codex for mango (at 0.7 ppm) and papaya (at 0.5 ppm). The tolerances for artichoke, barley, buckwheat, oats, and rye will not be harmonized with Codex for the following reasons. In the case of artichoke, Codex has set a lower MRL of 0.1 ppm based on field trials conducted with alpha-cypermethrin with a different use pattern, including a lower use rate and longer pre-harvest interval (PHI). The Agency's tolerance for artichoke of 0.6 ppm is supported by the submitted residue data, with a higher use rate and shorter PHI. In addition, for grains (barley, oats, buckwheat, and rye), the Codex MRLs assume a post-harvest treatment whereas the proposed use pattern in the United States is for pre-harvest treatment.

C. Response to Comments

A comment was received that objected to the proposed tolerances primarily because of the amounts of pesticides already consumed and carried by the American population.

The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, under the existing legal framework provided by FFDCA section 408, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-for Tolerances

The Agency has modified the levels for which tolerances are being established for artichoke, globe (0.80 to 0.60 ppm); barley, grain (1.7 to 3.0 ppm); barley, hay (5.0 to 6.0 ppm); barley, straw (19.0 to 20 ppm); buckwheat, grain (1.7 to 3.0 ppm); buckwheat, hay (5.0 to 6.0 ppm); buckwheat, straw (19.0 to 20.0 ppm); oat, grain (1.7 to 3.0 ppm); oat, hay (5.0 to 6.0 ppm); oat, straw (19.0 to 20.0 ppm); rye, grain (1.7 to 3.0 ppm); rye, hay (5.0 to 6.0 ppm); rye, straw (19.0 to 20.0 ppm); mango (0.45 to 0.70 ppm); and avocado; canistel; papaya; sapodilla; sapote, black; sapote, mamey; and star apple (0.45 to 0.50 ppm). These revisions are due to either EPA's use of the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures or to harmonize with Codex MRLs.

Also, EPA has revised the tolerance expression to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of zeta-cypermethrin not specifically mentioned.

2. That 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 the insecticide, zeta-cypermethrin, (*S*-cyano(3-phenoxyphenyl) methyl (±))(cis-trans 3-(2,2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate), including its metabolites and degradates in or on pistachio at 0.05 ppm; artichoke, globe at 0.60 ppm; barley, grain at 3.0 ppm; barley, hay at 6.0 ppm; barley, straw at 20 ppm; buckwheat, grain at 3.0 ppm; buckwheat, hay at 6.0 ppm; buckwheat, straw at 20.0 ppm; oat, grain at 3.0 ppm; oat, hay at 6.0 ppm; oat, straw at 20.0 ppm; rye, grain at 3.0 ppm; rye, hay at 6.0 ppm; rye, straw at 20.0 ppm; mango at 0.70 ppm; and avocado; canistel; papaya; sapodilla; sapote, black; sapote, mamey; and star apple at 0.50 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: November 30, 2012.

Lois Rossi,

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 § 180.418, revise the introductory text of paragraph (a)(2) and alphabetically add the following commodities to the table in paragraph (a)(2) to read as follows:

§ 180.418 Cypermethrin and an isomer zeta-cypermethrin; tolerances for residues.

(a) * * *

(2) Tolerances are established for residues of zeta-cypermethrin, (*S*-cyano(3-phenoxyphenyl) methyl (±))(cis-trans 3-(2,2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate), including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only total cypermethrin, cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate, in or on the commodity.

Commodity	Parts per million
* * * * *	
Artichoke, globe	0.60
Avocado	0.50
Barley, grain	3.0
Barley, hay	6.0
Barley, straw	20.0
* * * * *	
Buckwheat, grain	3.0
Buckwheat, hay	6.0
Buckwheat, straw	20.0
* * * * *	
Canistel	0.50
* * * * *	
Mango	0.70
* * * * *	
Oat, grain	3.0
Oat, hay	6.0
Oat, straw	20.0
* * * * *	
Papaya	0.50
* * * * *	
Pistachio	0.05
* * * * *	
Rye, grain	3.0
Rye, hay	6.0
Rye, straw	20.0
* * * * *	
Sapodilla	0.50
Sapote, black	0.50
Sapote, mamey	0.50
* * * * *	
Star apple	0.50
* * * * *	

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[FR Doc. 2012–29683 Filed 12–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0759; FRL–9371–3]

Buprofezin Pesticide Tolerances; Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of Wednesday, October 17, 2012, concerning buprofezin pesticide tolerances. This document corrects a typographical error.

DATES: This final rule correction is effective December 7, 2012.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0759, 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), EPA West 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: Amaris Johnson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–9542; email address: *johnson.amaris@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

The Agency included in the final rule a list of those who may be potentially affected by this action.

II. What does this technical correction do?

The preamble for FR Doc. 2012–25548 published in the **Federal Register** issue of Wednesday, October 17, 2012 (77 FR 63745) (FRL–9364–9) is corrected as follows: On page 63750, third column, under Unit IV. D., *Revisions to Petitoned-for Tolerances,* in the second paragraph, correct the last word in the paragraph, which now reads ''Logan'' to read ''Longan.''

III. Why is this correction issued as a final rule?

Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)) provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making this technical correction final without prior proposal and opportunity for comment, because it is