ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0311; FRL–9374–9]

Thiacloprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thiacloprid in or on pepper; cherry subgroup 12–12A; peach subgroup 12–12B; and plum subgroup 12–12C. Interregional Research Project Number 4 (IR–4) requested the stone fruit tolerance and Bayer CropScience requested the pepper tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 6, 2013. Objections and requests for hearings must be received on or before April 8, 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–2010–0311, 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–2010–0311 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 April 8, 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–2010–0311, by one of the following methods:

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

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

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of June 8, 2010 (75 FR 32463) (FRL–8827–5), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions by IR–4, 681 US Highway #1 South, North Brunswick, NJ 08902 (PP0E7704) and Bayer CropScience LLC, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709 (PP0F7706). The petitions requested that 40 CFR 180.594 be amended by establishing tolerances for residues of the insecticide thiacloprid ([3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene]cyanamide), in or on fruit, stone, group 12 at 0.5 parts per million (ppm) (PP0E7704) and pepper (bell and non-bell) at 1.1 ppm (PP0F7706). Bayer, in its petition (PP0F7706) also proposed to amend 40 CFR 180.594 for residues of thiacloprid by revising the tolerance expression under paragraph (a) to read: Tolerances are established for residues of thiacloprid, including its metabolites and degradates. Compliance with the tolerance levels specified is to be determined by measuring only thiacloprid ([3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene] cyanamide). That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which the tolerances are being established as well as some of the nomenclature. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a

reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for thiacloprid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with thiacloprid 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.

In mammalian systems, the liver appears to be the primary target organ of thiacloprid with some relatively minor effects in the thyroid. Liver effects (enzyme changes, hypertrophy, and histopathology) were noted in the 90-day dog, 2-generation reproduction, 2-year rat, 2-year mouse, and subchronic dermal and inhalation studies. Thyroid effects (hormone levels, weights, follicular cell hypertrophy) were noted in dog, rat, and mouse studies. Increased prostate weight and prostatic hypertrophy were observed in the 90-day dog study, but not in the 1-year dog study. Clinical signs were also noted in dermal (reduced motility, decreased activity, and spastic gait) and 5-day inhalation studies (respiratory effects, signs of ill health, piloerection, reduced mobility, tremors, and increased grip strength).

There was no increase in either qualitative or quantitative susceptibility of fetal animals or pups in the rabbit developmental or the 2-generation rat reproduction studies. In the rabbit developmental study, decreased fetal weights were observed in the presence of maternal toxicity (body weight changes and decreased food consumption and fecal output). In the reproduction study in rats, decreased body weights were seen in pups at the same dose which resulted in thyroid and liver effects in maternal animals.

In the rat developmental toxicity study, there was evidence of increased qualitative susceptibility. Increased resorptions; skeletal retardations and variations; dysplastic humerus, radius and scapulae; and decreased fetal weights were seen in fetuses at the same dose resulting in less severe maternal effects (decreased body weight, body weight gain and food consumption, increased urination, and changes in water consumption). In the developmental neurotoxicity study, increased qualitative susceptibility was also seen: Decreased body weights in both sexes as well as altered performance in passive avoidance testing were seen in offspring animals, while deceased body weight gain and food consumption were seen in maternal animals. However, there is a low degree of concern and no residual uncertainties for the increase in qualitative susceptibility since there are well-characterized dose responses with clear NOAELs and LOAELs in the studies. Additionally, the endpoints and PODs selected for risk assessment are protective of potential developmental effects.

Thiacloprid affects nerve function through inhibition of nicotinic acetylcholine receptors. In the neurotoxicity studies in rats, there was a reduction in motor and locomotor activity, slight tremors and ptosis of the eyelids, decreased hind limb grip strength, altered performance in passive avoidance testing, and altered brain morphometrics. Increased grip strength was also noted in a 5-day inhalation toxicity study. There were no indications of neurotoxicity in the remainder of the submitted toxicity studies.

A battery of genetic toxicity tests did not indicate a mutagenicity or clastogenicity concern. Thiacloprid is classified as ''Likely to be Carcinogenic to Humans'' based on increased uterine tumors in rats, thyroid follicular adenomas in rat and ovarian tumors in mice. A cancer slope factor of 4.06×10^{-2} milligrams/kilogram/day (mg/kg/day)$^{-1}$ was calculated based on the incidence of combined uterine tumors in female rats.

Specific information on the studies received and the nature of the adverse effects caused by thiacloprid 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* on pages 29–34 of the document titled ''Thiacloprid—Human Health Risk Assessment of New Uses on Stone Fruit and Peppers'' in docket ID number EPA–HQ–OPP–2010–0311.

B. Toxicological Points of Departure/Levels of Concern

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

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

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIACLOPRID 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 (All Populations)	NOAEL = 4.4 mg/kg/day .. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.044 mg/kg/day .... aPAD = 0.044 mg/kg/day	Co-Critical Studies Developmental Neurotoxicity Study—rat LOAEL = 25.6 mg/kg bw based on offspring effects of altered performance in passive avoidance testing. Acute Neurotoxicity Study—rat LOAEL = 22 mg/kg bw based on a reduction of motor and locomotor activity in females (NOAEL = 3.1 mg/kg bw).
Chronic dietary (All populations) ..	NOAEL = 1.2 mg/kg/day .. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.012 mg/kg/day cPAD = 0.012 mg/kg/day	Chronic/Carcinogenicity Study—rat LOAEL = 2.5/3.3 (M/F) mg/kg bw based on liver hypertrophy and cytoplasmic changes as well as induction of enzymes, thyroid epithelial hypertrophy in males and retinal degeneration in females.
Cancer (Oral, dermal, inhalation)	''Likely to be Carcinogenic to Humans'' based on thyroid tumors in male rats, uterine tumors in rats and ovarian tumors in mice. Cancer slope factor = 4.06×10^{-2} $(mg/kg/day)^{-1}$		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. mg/kg/day = milligrams/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). 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 thiacloprid, EPA considered exposure under the petitioned-for tolerances as well as all existing thiacloprid tolerances in 40 CFR 180.594. EPA assessed dietary exposures from thiacloprid 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 thiacloprid. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA), National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. The acute assessment was based on tolerance-level residues and 100 percent crop treated (PCT) assumptions.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA. This dietary survey was conducted from 2003 to 2008. The chronic assessment was based on tolerance-level residues and 100 PCT assumptions.

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. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer 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. Based on the data summarized in Unit III.A., EPA has concluded that thiacloprid should be classified as ''Likely to be Carcinogenic to Humans'' and a linear approach has been used to quantify cancer risk.

The cancer analysis is partially refined, using average residue field trial data, and estimated PCT data for existing and proposed new uses as appropriate.

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.

In the cancer risk assessment, the Agency estimated the PCT for existing uses as follows: Apples, 10%; pears, 5%.

In most cases, EPA uses available data from USDA/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%.

In the cancer risk assessment, the Agency estimated the PCT for new uses as follows: Peaches, 43%; peppers, 45%.

EPA estimates of the PCT for new uses of thiacloprid represent the upper bound of use expected during the pesticide's initial 5 years of registration; that is, PCT for new uses for thiacloprid is a threshold of use that EPA is reasonably certain will not be exceeded for each registered use site. The PCT for new uses recommended for use in the chronic dietary assessment is calculated as the average PCT of the market leader or leaders, (*i.e.,* the one(s) with the greatest PCT) on that site over the three most recent years of available data. The PCT for new uses recommended for use in the acute dietary assessment is the maximum observed PCT over the same period. Comparisons are only made among pesticides of the same pesticide types (*e.g.,* the market leader for insecticides on the use site is selected for comparison with a new insecticide). The market leader included in the estimation may not be the same for each year since different pesticides may dominate at different times.

Typically, EPA uses USDA/NASS as the source data because it is publicly available and directly reports values for PCT. When a specific use site is not reported by USDA/NASS, EPA uses proprietary data and calculates the PCT given reported data on acres treated and acres grown. If no data are available, EPA may extrapolate PCT for new uses from other crops, if the production area and pest spectrum are substantially similar.

A retrospective analysis to validate this approach shows few cases where the PCT for the market leaders were exceeded. Further review of these cases identified factors contributing to the exceptionally high use of a new pesticide. To evaluate whether the PCT for new uses for thiacloprid could be exceeded, EPA considered whether there may be unusually high pest pressure, as indicated in emergency exemption requests for thiacloprid; the pest spectrum of the new pesticide in comparison with the market leaders and whether the market leaders are well established for that use; and whether pest resistance issues with past market leaders provide thiacloprid with significant market potential. Given currently available information, EPA concludes that it is unlikely that actual PCT for thiacloprid will exceed the estimated PCT for new uses during the next 5 years.

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 thiacloprid 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 thiacloprid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of thiacloprid. The drinking water estimates were also refined to account for both percent cropped area and for the impact of drinking water treatment processes. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of thiacloprid for acute exposures are estimated to be 18 parts per billion (ppb) for surface water and 0.25 ppb for ground water, for chronic exposures for non-cancer assessments are estimated to be 2.3 ppb for surface water and 0.25 ppb for ground water, and for chronic exposures for cancer assessments are estimated to be 1.2 ppb for surface water and <0.25 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 18 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 2.3 ppb was used to assess the contribution to drinking water. For the cancer dietary risk assessment, the water concentration of value 1.2 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).

Thiacloprid is not registered for any specific use patterns that would result in residential exposure.

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.''

EPA has not found thiacloprid to share a common mechanism of toxicity with any other substances, and thiacloprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that thiacloprid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity

and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no increase in either qualitative or quantitative susceptibility of fetal animals or pups in the rabbit developmental or the 2-generation rat reproduction studies. In the rabbit developmental study, decreased fetal weights were observed in the presence of maternal toxicity (body weight changes and decreased food consumption and fecal output). In the reproduction study in rats, decreased body weights were seen in pups at the same dose which resulted in thyroid and liver effects in maternal animals.

In the rat developmental study, there was an increase in qualitative susceptibility based on an increase in resorptions, skeletal retardations and variations, dysplastic humerus, radius and scapulae, as well as decreased fetal weights at the same dose (50 mg/kg/day) at which less severe maternal effects were noted (decreased body weight, body weight gain and food consumption, in addition to increased urination and changes in water consumption). In the developmental neurotoxicity study, increased qualitative susceptibility was also seen. Decreased body weights in both sexes as well as altered performance in passive avoidance testing were seen in offspring animals, while decreased body weight gain and food consumption were seen in maternal animals. However, there is a low degree of concern and no residual uncertainties for the increase in qualitative susceptibility since there is a well-characterized dose response with clear NOAELs and LOAELs in the studies. Additionally, the endpoints and PODs selected for risk assessment are protective of potential developmental effects.

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 1x. That decision is based on the following findings:

i. The toxicology database concerning infants and children is considered to be complete with the exception of an immunotoxicity study. Submitted studies included: Developmental rat and rabbit, 2-generation reproduction in rats as well as acute, subchronic and developmental neurotoxicity in rats. Although an immunotoxicity study has not been received by the Agency, there is relatively little concern as it does not appear that thiacloprid directly targets the immune system based on available studies. Although there were increases in the incidence and severity of mesenteric and mandibular lymph node vacuolization in a cancer study in mice, the effects were seen at very high doses following long-term treatment. Additionally, thiacloprid does not belong to a class of chemicals (*e.g.,* the organotins, heavy metals, halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Furthermore, there were no indications of immunotoxicity in other studies in the toxicology database. The Agency does not believe that conducting the study will result in a lower POD than that currently used for overall risk assessment; therefore, a database uncertainty factor (UF_{DB}) is not needed to account for the lack of the study.

ii. Acute, subchronic and developmental neurotoxicity studies in rats are available for thiacloprid. In the acute study, there were reductions in motor and locomotor activities in females and slight tremors and ptosis of the eyelids in males. In the subchronic neurotoxicity study, decreased hind limb grip strength was seen in males. Increased grip strength was noted in a 5-day inhalation toxicity study. In the developmental neurotoxicity study, altered performance in passive avoidance testing and a 4% decrease in the size of the corpus striatum region of the brain were seen in offspring animals at the highest dose tested (HDT). No data were received by the Agency regarding the mid- and low-dose brain measurements. However, the lack of a NOAEL for brain morphometric measurements in this study does not warrant an additional uncertainty factor since the decrease in weight at the high dose is considered marginal and variable, and a lower dose would most likely result in less of an effect (the HDT was 10x greater than the lowest dose tested), and the endpoints and PODs selected for risk assessment are protective of the slight morphometric changes observed at the high dose. Even if a 10x factor is applied to the dose where the slight morphometric changes were seen in the developmental neurotoxicity study, the result would be a POD comparable to those currently selected for risk assessment. Therefore, the PODs currently selected are protective of any potential effects. There were no indications of neurotoxicity in the remainder of the submitted toxicity studies.

iii. As noted in Unit III.D.2., although there was an increase in qualitative susceptibility in the rat developmental study and developmental neurotoxicity study, there is a low degree of concern and no residual uncertainties for the increase in qualitative susceptibility since there is a well-characterized dose response with clear NOAELs and LOAELs.

iv. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. The cancer assessment used PCT and anticipated residues for new and registered uses. This is based on reliable data and will not underestimate the exposure and risk. The drinking water residues used in this assessment were partially refined to account for PCT area and drinking water treatment processes. However, these drinking water estimates are still considered to be conservative and upper-bound. These assessments will not underestimate the exposure and risks posed by thiacloprid.

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 thiacloprid will occupy 19% of the aPAD for infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to thiacloprid from food and water will utilize 26% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for thiacloprid.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water

(considered to be a background exposure level).

Short- and intermediate-term adverse effect was identified; however, thiacloprid is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for thiacloprid.

4. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions described in this unit for cancer, EPA has concluded that the cancer risk estimate from exposure to thiacloprid through food and water for the U.S. population is 2×10^{-6}, which is below the Agency's level of concern.

EPA generally considers cancer risks in the range of 10^{-6} or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. Here, substantial conservatism is incorporated by the use of food residue values from field trial studies using maximum application procedures and upper-bound modeled drinking water residues in the exposure assessment. Accordingly, EPA has concluded the cancer risk for all existing thiacloprid uses and the uses associated with the tolerances established in this action fall within the range of 1×10^{-6} and are thus negligible.

5. *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 thiacloprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography-mass spectrometer/mass spectrometer (HPLC–MS/MS)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

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

The Codex has established MRLs for thiacloprid in or on sweet peppers (including pimento or pimiento) at 1 ppm and stone fruit, crop group 12 at 0.5 ppm. These MRLs are the same as the tolerances being established for thiacloprid in the United States on these crops.

C. Revisions to Petitioned-for Tolerances

The Agency has modified the level at which the tolerance is being established for pepper from the proposed level of 1.1 ppm to 1.0 ppm in order to harmonize with the Codex MRL.

EPA has also revised the request for a tolerance for thiacloprid on the stone fruit group 12. Subsequent to the filing of the petition requesting a stone fruit group 12 tolerance, EPA issued a final rule that revised the crop grouping regulations (77 FR 50617, August 22, 2012) (FRL–9354–3). As part of this action, EPA expanded and revised the existing stone fruit group 12. Changes to crop group 12 included adding the following commodities: Japanese apricot, capulin, black cherry, nanking cherry, Chinese jujube, American plum, beach plum, Canada plum, cherry plum, Klamath plum, and sloe; creating new subgroups (the cherry subgroup 12–12A, the peach subgroup 12–12B, and the plum subgroup 12–12C); and naming the new crop group ''Crop Group 12–12: Stone Fruit Group.'' EPA indicated in the August 22, 2012 final rule as well as the earlier November 9, 2011 proposed rule (76 FR 69693) (FRL–8887–8) that, for existing petitions for which a notice of filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, and upon review of the petition, the Agency concluded that it was appropriate to establish tolerances for the cherry subgroup 12–12A and the peach subgroup 12–12B at 0.5 ppm, and the plum subgroup 12–12C at 0.05 ppm. A single tolerance for the entire stone fruit group 12–12 could not be established due to the significantly different residue levels in the trials with plums as compared to the other representative commodities in the stone fruit crop group and thus tolerances were established for each of the three separate subgroups.

V. Conclusion

Therefore, tolerances are established for residues of the insecticide thiacloprid, including its metabolites and degradates, in or on pepper at 1.0 ppm; cherry subgroup 12–12A at 0.5 ppm; peach subgroup 12–12B at 0.5 ppm; plum subgroup 12–12C at 0.05 ppm. Compliance with the tolerance levels is to be determined by measuring only thiacloprid, (Z)-[3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene]cyanamide.

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: January 29, 2013.

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

§ 180.594 Thiacloprid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide thiacloprid, 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 thiacloprid ([3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene] cyanamide) in or on the commodity.

Commodity	Parts per million
* * * * *	
Cherry subgroup 12–12A ...	0.5
* * * * *	
Peach subgroup 12–12B	0.5
Pepper	1.0
Plum subgroup 12–12C	0.05
* * * * *	

* * * * *

[FR Doc. 2013–02692 Filed 2–5–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

[Docket ID FEMA–2013–0002]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Modified Base (1% annual-chance) Flood Elevations (BFEs) are finalized for the communities listed below. These modified BFEs will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective dates for these modified BFEs are indicated on the following table and revise the Flood Insurance Rate Maps (FIRMs) in effect for the listed communities prior to this date.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below of the modified BFEs for each community listed. These modified BFEs have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified BFEs are not listed for each community in this notice. However, this final rule includes the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection.

The modified BFEs are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.