



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0784; FRL-10004-12]

Acetamiprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acetamiprid in or on multiple commodities that 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 [*insert date of publication in the Federal Register*].

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

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0784, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing 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-2018-0784 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0784, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 19, 2019 (84 FR 16430) (FRL-9991-14), 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 8E8715) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of acetamiprid, (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanimidamide, including its metabolites and degradates in or on the following raw agricultural commodities: tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B at 0.50 parts per million (ppm); leafy greens subgroup 4-16A at 3.0 ppm; leaf petiole vegetable subgroup 22B at 3.0 ppm; celtuce at 3.0 ppm; Florence fennel at 3.0 ppm; *Brassica*, leafy greens, subgroup 4-16B at 15 ppm; Vegetable, *Brassica*, head and stem, group 5-16 at 1.2 ppm; kohlrabi at 1.2 ppm; fruit, stone, group 12-12 at 1.5 ppm; nut, tree, group 14-12 at 0.10 ppm; rapeseed subgroup 20A at 0.01 ppm; and cottonseed subgroup 20C at 0.70 ppm.

Additionally, the petition requested to amend 40 CFR 180.578 by removing the established tolerances for residues of acetamiprid in or on the following raw agricultural commodities: vegetable, leafy, except *Brassica*, group 4 at 3.00 ppm; *Brassica*, leafy greens, subgroup 5B at 15 ppm; turnip, greens at 15 ppm; *Brassica*, head and stem, subgroup 5A at 1.20 ppm; fruit, stone, group 12, except plum, prune at 1.20 ppm; plum, prune, fresh at 0.20 ppm; nut, tree, group 14 at 0.10 ppm; pistachio at 0.10 ppm; canola, seed at 0.010 ppm; mustard, seed at 0.010 ppm; and cotton, undelinted seed at 0.60 ppm.

That document referenced a summary of the petition prepared by Nippon Soda Co., Ltd. c/o Nisso America Inc, the registrant, which is available in the docket,

<http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Pursuant to its authority in FFDCCA section 408(d)(4)(A)(i), EPA is establishing tolerances that vary slightly from what the petitioner requested. The reasons for these changes are in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCCA 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 FFDCCA 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 FFDCCA 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 FFDCCA section 408(b)(2)(D), and the factors specified in FFDCCA 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 acetamiprid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with acetamiprid 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 all species tested, generalized nonspecific toxicity was observed as decreases in body weight/body weight gain, food consumption, and food efficiency. Hepatocellular hypertrophy was observed in both mice and rats, and hepatocellular vacuolation in the rat, but these liver effects alone are considered adaptive and not indicative of an adverse effect. Other effects observed in the oral studies include amyloidosis of multiple organs in the mouse carcinogenicity study, tremors in high dose females in the mouse subchronic study, and micro-concretions in the kidney papilla and mammary hyperplasia in the rat chronic/carcinogenicity study.

Acetamiprid is rapidly absorbed, metabolized, and eliminated. The metabolism study in rats indicates 96-99% absorption following an oral administration. Peak blood concentrations in the rat occur within 1-2 hours at the low dose (1 mg/kg), 3-6 hours post-dosing at the high dose (50 mg/kg), and the main route of excretion is through the urine, which is nearly complete by 48 hours for all doses. Metabolites of acetamiprid account for 79-86% of the administered radioactivity, with 6-Chloronicotinic (IC-O) acid being the most abundant metabolite. There were no significant sex differences noted in the ADME profile in rats.

No effects were observed in the 21-day dermal study in the rabbit and no inhalation studies were conducted. EPA has used a refined value of 10% as a dermal absorption factor based on the rat dermal absorption study and weight of evidence.

Evidence of qualitative susceptibility was observed in the 2-generation reproductive study, with the offspring effects (significant reductions in pup weights, reduction in litter size

and viability, significant delays in weaning indices and the age to attain vaginal opening and preputial separation) considered more severe than the decrease in parental body weights.

Qualitative susceptibility was also seen in the developmental neurotoxicity study (DNT) with offspring effects (decreased body weight, pre-weaning survival, and startle response) occurring in the presence of marginal parental body weight decreases.

Evidence of neurotoxicity was observed in the rat acute neurotoxicity study (decrease in locomotor activity, and at higher doses: tremors, difficulty in handling, walking on toes, dilated pupils, chewing, coldness to the touch, abnormal gaits and/or posture, decreased forelimb grip strength, and hind limb foot splay), subchronic toxicity study in mice (tremors), the DNT (decreased startle response), and comparative metabolism study (decreased alertness, reactivity, spontaneous activity, locomotor activity, rearing, muscle tone, and grip strength; as well as tremors, staggering, and depressed reflexes in the rat, mouse, and/or rabbit). Subchronic immunotoxicity studies were performed in both sexes in rats and mice, with no effects on the immune system observed up to the highest dose tested. Acetamiprid and its metabolites IC-0, IM-1-2, IM-1-4, IM-2-1, and IM-0 tested negative for mutagenicity. With no treatment-related tumors seen in rats or mice, the Agency has classified acetamiprid as not likely to be carcinogenic to humans.

Specific information on the studies received and the nature of the adverse effects caused by acetamiprid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document titled “Acetamiprid. Human Health Risk Assessment for Proposed Use on Tropical and Subtropical, Medium to Large Fruit, Smooth, Inedible Peel Subgroup 24B; Greenhouse-grown Peppers; and Crop Group Conversions and

Expansions” on pages 38-43 in docket ID number EPA-HQ-OPP-2018-0784.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

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

Table 1. Summary of Toxicological Doses and Endpoints for Acetamiprid for Use in FFDCA 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 = 10 mg/kg/day UF _A = 10X	Acute RfD = 0.1	Co-critical studies <u>Developmental Neurotoxicity in rat</u>

	UF _H = 10X FQPA SF = 1X	mg/kg/day aPAD = 0.1 mg/kg/day	LOAEL = 45 mg/kg/day based on decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males. <u>Acute Neurotoxicity Study in rat</u> LOAEL = 30 mg/kg/day based on decreased locomotor activity.
Chronic dietary (All populations)	NOAEL= 7.1 mg/kg/day UF _A = 10X UF _H = 10X FQPA SF = 1X	Chronic RfD = 0.071 mg/kg/day cPAD = 0.071 mg/kg/day	<u>Chronic Toxicity/Carcinogenicity Study in rats</u> LOAEL = 17.5 mg/kg/day based on decreased body weight and body weight gains in females and hepatocellular vacuolation in males.
Incidental oral short-term (1 to 30 days)	NOAEL= 10 mg/kg/day UF _A = 10X UF _H = 10X FQPA SF = 1X	LOC for MOE = 100	<u>Developmental Neurotoxicity in rat</u> LOAEL = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males.
Incidental oral long-term (greater than 6 months)	NOAEL= 7.1 mg/kg/day UF _A = 10X UF _H = 10X FQPA SF = 1X	LOC for MOE = 100	<u>Chronic Toxicity/Carcinogenicity Study in rats</u> LOAEL = 17.5 mg/kg/day based on decreased body weight and body weight gains in females and hepatocellular vacuolation in males.
Dermal short- and intermediate-term (1 to 30 days; 1 to 6 months)	Oral study NOAEL = 10 mg/kg/day UF _A = 10X UF _H = 10X DAF = 10% FQPA SF = 1X	LOC for MOE = 100	<u>Developmental Neurotoxicity in rat</u> LOAEL = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males.
Dermal long-term (greater than 6 months)	Dermal (or oral) study NOAEL= 7.1 mg/kg/day UF _A = 10X UF _H = 10X DAF = 10% FQPA SF = 1X	LOC for MOE = 100	<u>Chronic Toxicity/Carcinogenicity Study in rats</u> LOAEL = 17.5 mg/kg/day based on decreased body weight and body weight gains in females and hepatocellular vacuolation in males.
Inhalation short-term (1 to 30 days)	Oral study NOAEL= 10 mg/kg/day Inhalation toxicity assumed to be equivalent to oral toxicity UF _A = 10X UF _H = 10X FQPA SF = 1X	LOC for MOE = 100	<u>Developmental Neurotoxicity in rat</u> LOAEL = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be carcinogenic to humans"		

FQPA SF = Food Quality Protection Act Safety Factor. 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, 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). DAF = Dermal Absorption Factor.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acetamiprid, EPA considered exposure under the petitioned-for tolerances as well as all existing acetamiprid tolerances in 40 CFR 180.578. EPA assessed dietary exposures from acetamiprid 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 acetamiprid. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the acute dietary exposure assessment was unrefined and used tolerance-level residues and 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 2003-2008 NHANES/WWEIA. As to residue levels in food, the chronic dietary exposure assessment was slightly refined using PCT information for some commodities. Aside from these commodities, the analyses were based on tolerance-level residues and the assumption of 100 PCT. In addition, conservative default processing factors were used for many processed commodities, while empirical processing factors were used for a

limited number of processed commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that acetamiprid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(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 and the exposure estimate does not understate exposure for the population in such area.

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

The Agency estimated the PCT for existing uses as follows:

In the acute assessment, 100 PCT was assumed for all commodities.

In the chronic assessment, the PCT estimates used were as follows: 1% of almonds, 30% of apples, 10% of apricots, 5% of asparagus, 10% of blueberries, 5% of broccoli, 10% of cabbage, 5% of caneberries, 15% of cantaloupes, 10% of cauliflower, 40% of celery, 5% of cherries, 5% of cotton, 2.5% of cucumbers, 2.5% of grapefruit, 2.5% of grapes, 2.5% of lemons, 15% of lettuce, 1% of nectarines, 2.5% of onions, 2.5% of oranges, 5% of peaches, 35% of

pears, 1% of pecans, 5% of peppers, 5% of pistachios, 2.5% plums/prunes, 2.5% of potatoes, 5% of pumpkins, 10% of spinach, 5% of squash, 30% of strawberries, 1% of sweet corn, 5% of tomatoes, 15% of walnuts, and 5% of watermelons.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute 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 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

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 acetamiprid 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 acetamiprid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acetamiprid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Pesticide in Water Calculator (PWC) and Provisional Cranberry Model, the estimated drinking water concentrations (EDWCs) of acetamiprid for acute exposures are estimated to be 88.1 parts per billion (ppb) in surface water and 211 ppb in ground water, and for chronic exposures are estimated to be 12.7 ppb in surface water and 175 ppb in 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 211 ppb was used to assess the contribution from drinking water. For the chronic dietary risk assessment, the water concentration of value 175 ppb was used to assess the contribution from 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).

Acetamiprid is currently registered for the following uses that could result in residential exposures: gardens and trees, spot-on pet treatment, fly control, indoor crack/crevice, mattresses for bed bug control, and animal barns. EPA assessed residential exposure using the following assumptions: Residential handler dermal and inhalation exposure are expected to occur from the use of the registered acetamiprid formulations on ornamentals, vegetables, and fruit trees. All residential handler exposures are expected to be short-term in duration. Residential handler dermal exposure is expected to occur from the registered acetamiprid spot-on product when applied to dogs. Inhalation exposure from spot-on products is considered to be negligible. Residential handler dermal and inhalation exposures from applications to indoor environments was not assessed based on current Agency policy because the labels for the products that are used in indoor environments require personal protective equipment (PPE). Residential handler exposure from the fly bait use was not assessed, as exposures are expected to be insignificant due to incorporation of acetamiprid in the glue.

There is the potential for post-application exposure for individuals exposed as a result of being in an environment that has been treated with acetamiprid. The quantitative risk assessment for residential post-application exposures is based on the following scenarios: short-term dermal exposure to gardens (gardens, trees, indoor plants); short-, intermediate-, and long-term dermal and incidental oral exposure to the dog spot-on treatment; short-term dermal, inhalation, and incidental oral exposure from the indoor crack and crevice and bed bug mattress uses; and short-term dermal and incidental oral exposure from the fly bait granule use. Post-application dermal exposures from foundation, perimeter, and spot treatments outdoors, along with post-application inhalation exposure, are considered negligible and were not assessed. Acetamiprid is also

registered for use as a termiticide. A quantitative assessment for potential post-application inhalation and dermal exposure resulting from a commercial termiticide application in a residential setting is not needed, as all applications are made to the soil/foundation around/underneath a structure. In this case, exposure to acetamiprid vapors is not expected. Additionally, EPA believes that inhalation and dermal exposure to acetamiprid from bed bug treatments (applied directly to the space where people are living vs. application to the foundation/structure) would be protective of the termiticide uses of acetamiprid.

The lifestages selected for each post-application scenario are based on the Agency's 2012 Residential SOPs. While not the only lifestage potentially exposed for these post-application scenarios, the lifestage that is included in the quantitative assessment, (i.e., Children (1 < 2 years), children (3 < 6 years), children (6 < 12 years), adult), is health protective for the exposures and risk estimates for any other potentially exposed lifestage.

Based on the proposed uses, short- and intermediate-term exposures are expected for the proposed use profile. Since the same endpoint and POD were selected for short- and intermediate-term durations, short-term exposure and risk estimates are considered protective of potential intermediate-term exposure and risk.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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 acetamiprid to share a common mechanism of toxicity with any other substances, and acetamiprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that acetamiprid 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 website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

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.* Evidence of qualitative susceptibility was observed in the 2-generation reproductive study, with the offspring effects (significant reductions in pup weights, reduction in litter size and viability, significant delays in weaning indices and the age to attain vaginal opening and preputial separation) considered more severe than the decrease in parental body weights. Qualitative susceptibility was also seen in the DNT with offspring effects

(decreased body weight, pre-weaning survival, and startle response) occurring in the presence of marginal parental body weight decreases.

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 toxicity database for acetaminophen is complete.

ii. Acetaminophen produced signs of neurotoxicity in the high dose groups in the acute and developmental neurotoxicity studies in rats and the subchronic toxicity study in mice. However, no neurotoxic findings were reported in the subchronic neurotoxicity study in rats. Additionally, there are clear NOAELs identified for the effects observed in the toxicity studies. The doses and endpoints selected for risk assessment are protective and account for all toxicological effects observed in the database.

iii. No quantitative or qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to acetaminophen was observed in the developmental toxicity study in either rats or rabbits. Although increased qualitative susceptibility was seen in the reproduction toxicity and the DNT study, the degree of concern for the effects is low. There are clear NOAELs for the offspring effects and regulatory doses were selected to be protective of these effects. No other residual uncertainties were identified with respect to susceptibility. The endpoints and doses selected for acetaminophen are protective of adverse effects in both offspring and adults.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues, and the chronic dietary exposure assessment was slightly refined using PCT information for some commodities. EPA made conservative (protective) assumptions in the ground and surface

water modeling used to assess exposure to acetamiprid in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by acetamiprid.

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 acetamiprid will occupy 89% of the aPAD for children 1 to 2 years 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 acetamiprid from food and water will utilize 48% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

Long-term aggregate risk assessments were conducted to assess risks for adults and children and include exposure through oral (children only) and dermal routes. The oral and dermal endpoints for long-term exposure durations are the same (decreased body weight and body weight gains), and therefore exposures from these pathways are aggregated. In accordance with the FQPA, the combined exposure from these pathways is added to the background dietary

exposure from the chronic dietary exposure assessment.

The Agency selected only the most conservative, or worst case, scenarios for each lifestage. For both adults and children, worst-case long-term scenarios reflect post-application exposure to pets treated with spot-on products. As the LOCs are identical for all routes of exposure, and since the POD for all routes of exposure is derived from an oral study, the long-term aggregate MOEs were calculated by adding the exposures and dividing the POD (7.1 mg/kg) by the sum of the exposures.

EPA has concluded the combined long-term food, water, and residential exposures result in aggregate MOEs of 110 for children 1 to less than 2 years old and 360 for adults. Because EPA's level of concern for acetamiprid is a MOE of 100 or below, these MOEs are not of concern.

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).

Acetamiprid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to acetamiprid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 180 for adults, 460 for children 6 to less than 12 years old, 340 for children 3 to less than 6 years old, and 130 for children 1 to less than 2 years old. Because EPA's level of concern for acetamiprid is a MOE of 100 or below, these MOEs 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 adverse effect was identified, and intermediate-term exposure is expected; however, since the same endpoint and POD were selected for short- and intermediate-term durations, short-term exposure and risk estimates are considered protective of potential intermediate-term exposure and risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, acetamiprid is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to acetamiprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Approved tolerance enforcement methods for acetamiprid residues in crops are available, including methods using gas chromatography with electron capture detection (GC/ECD) analysis for vegetables and non-citrus fruits, high-performance liquid chromatography with ultraviolet detection (HPLC/UV) analysis for citrus fruits only, and HPLC with tandem mass spectrometric detection (LC/MS/MS) analysis for vegetables and non-citrus fruits. An approved HPLC/UV tolerance enforcement method for livestock matrices is available.

The methods 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 following table summarizes the tolerances being established by this document and the corresponding Codex tolerances. The U.S. tolerance in Cottonseed subgroup 20C is harmonized with the Codex MRL in cotton seed. The U.S. tolerance in Fruit, stone, group 12-12 is harmonized with the Codex MRL in cherry, which has the highest MRL of the individual group 12-12 commodities with Codex MRLs. EPA is not able to harmonize the other tolerances with Codex MRLs because the U.S. tolerances are higher. Establishing a U.S. tolerance at a lower level to harmonize with Codex would put U.S. growers at risk of having violative residues despite legal use of the pesticide according to the label.

U.S. tolerances established in this rulemaking (40 CFR §180.578)		Codex	
Commodity	Tolerance (ppm)	Commodity	MRL (mg/kg)
<i>Brassica</i> , leafy greens, subgroup 4-16B	15	Chinese broccoli	0.4
Celtuce	3	--	--
Cottonseed subgroup 20C	0.7	Cotton seed	0.7
Florence, fennel, fresh leaves and stalk	3	--	--
Fruit, stone, group 12-12	1.5	Cherry	1.5

		Nectarine, peach	0.7
		Dried prune	0.6
		Plum	0.2
Kohlrabi	1.2	--	--
Leaf petiole vegetable subgroup 22B	3	Celery	1.5
Leafy greens subgroup 4-16A	3	--	--
Nut, tree, group 14-12	0.1	Tree nuts	0.06
Rapeseed subgroup 20A	0.01	--	--
Tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B	0.5	--	--
Vegetable, <i>brassica</i> , head and stem, group 5-16	1.2	Broccoli, cauliflower Cabbage	0.4 0.7

C. Response to Comments

One commenter stated that “EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions.” The commenter does not indicate what additional data might be necessary, why the commenter questions the sufficiency of the available data, or what about the Agency’s findings is unsupported. Contrary to the commenter’s position, the Agency has in fact fully evaluated all the data submitted on acetamiprid and determined that the toxicological and exposure databases on acetamiprid are complete, i.e., they do not contain any data gaps at this time, and dietary and residential exposure and risk have not been underestimated. Taking all that information into consideration, EPA has concluded that the tolerances for acetamiprid are safe.

The other comments submitted raised more general concerns about the use of pesticides and questioned a separate tolerance exemption. Neither raise issues relevant to this tolerance rulemaking.

D. Revisions to Petitioned-For Tolerances

EPA is establishing some of the tolerances at different levels than petitioned for in order to be consistent with the Agency’s rounding class practice, which is based on the rounding procedures of the Organisation for Economic Co-operation and Development. EPA corrected the

commodity definition for Fennel, Florence, fresh leaves and stalk. Finally, EPA is removing the existing tolerance in Plum, prune, dried, because it is no longer needed with the establishment of the tolerance in Fruit, stone, group 12-12; although not requested in the original petition, the need to remove this tolerance was confirmed in subsequent correspondence with the petitioner.

V. Conclusion

Therefore, tolerances are established for residues of acetamiprid in or on *Brassica*, leafy greens, subgroup 4-16B at 15 ppm; Celtuce at 3 ppm; Cottonseed subgroup 20C at 0.7 ppm; Fennel, Florence, fresh leaves and stalk at 3 ppm; Fruit, stone, group 12-12 at 1.5 ppm; Kohlrabi at 1.2 ppm; Leaf petiole vegetable subgroup 22B at 3 ppm; Leafy greens subgroup 4-16A at 3 ppm; Nut, tree, group 14-12 at 0.1 ppm; Rapeseed subgroup 20A at 0.01 ppm; Tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B at 0.5 ppm; and Vegetable, *brassica*, head and stem, group 5-16 at 1.2 ppm.

Additionally, the following existing tolerances are removed as unnecessary due to the establishment of the above tolerances: *Brassica*, head and stem, subgroup 5A; *Brassica*, leafy greens, subgroup 5B; Canola, seed; Cotton, undelinted seed; Fruit, stone, group 12, except plum, prune; Mustard, seed; Nut, tree, group 14; Pistachio; Plum, prune, dried; Plum, prune, fresh; Turnip greens; and Vegetable, leafy, except *brassica*, group 4.

VI. Statutory and Executive Order Reviews

This action establishes and modifies tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211,

entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In

addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 24, 2020.

Michael Goodis,

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 § 180.578, amend the table in paragraph (a)(1) as follows:

- a. Remove the entries for “*Brassica*, head and stem, subgroup 5A” and “*Brassica*, leafy greens, subgroup 5B”;
- b. Add alphabetically the entry “*Brassica*, leafy greens, subgroup 4-16B”;
- c. Remove the entry for “Canola, seed”;
- d. Add alphabetically the entries “Celtuce” and “Cottonseed subgroup 20C”;
- e. Remove the entry for “Cotton, undelinted seed”;
- f. Add alphabetically the entries “Fennel, florence, fresh leaves and stalk” and “Fruit, stone, group 12-12”;
- g. Remove the entry for “Fruit, stone, group 12, except plum, prune”;
- h. Add alphabetically the entries “Kohlrabi”; “Leaf petiole vegetable subgroup 22B”; and “Leafy greens subgroup 4-16A”;
- i. Remove the entries for “Mustard, seed” and “Nut, tree, group 14”;
- j. Add alphabetically the entry “Nut, tree, group 14-12”;
- k. Remove the entries for “Pistachio”; “Plum, prune, dried”; and “Plum, prune, fresh”;
- l. Add alphabetically the entries “Rapeseed subgroup 20A” and “Tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B”;
- m. Remove the entry for “Turnip greens”;
- n. Add alphabetically the entry “Vegetable, *brassica*, head and stem, group 5-16”; and

o. Remove the entry for “Vegetable, leafy, except brassica, group 4”.

The revisions and additions read as follows:

§ 180.578 Acetamiprid; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
<i>Brassica</i> , leafy greens, subgroup 4-16B	15
* * * * *	
Celtuce	3
* * * * *	
Cottonseed subgroup 20C	0.7
Fennel, florence, fresh leaves and stalk	3
* * * * *	
Fruit, stone, group 12-12	1.5
* * * * *	
Kohlrabi	1.2
Leaf petiole vegetable subgroup 22B	3
Leafy greens subgroup 4-16A	3
Nut, tree, group 14-12	0.1
* * * * *	
Rapeseed subgroup 20A	0.01
* * * * *	
Tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B	0.5
Vegetable, <i>brassica</i> , head and stem, group 5-16	1.2
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