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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0037; FRL-9987-32]

Abamectin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of abamectin in or on bananas and tea. Syngenta Crop Protection, LLC, 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-2018-0037, 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 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-2018-0037 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-2018-0037, 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 11, 2018 (83 FR 15528) (FRL-9975-57), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 7E8636 and 7E8637) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide avermectin B1 (a mixture of avermectins containing greater than or equal to 80% avermectin B1a (5-*O*-demethyl avermectin A1) and less than or equal to 20% avermectin B1b (5-*O*-demethyl -25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A1)) in or on the raw agricultural commodities tea (7E8636) at 1 parts per million (ppm) and banana at 0.002 ppm (7E8637). That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, <http://www.regulations.gov>. Two comments were received on the notice of filing; however, neither comment refers to abamectin in particular or pesticides in general, and are therefore not relevant to this action.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established for tea and banana as well as the commodity definition for tea. The reason for these changes are 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 abamectin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with abamectin 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.

A summary of the toxicological effects of abamectin as well as specific information on the studies received and the nature of the adverse effects caused by abamectin and the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of May 2, 2016 (81 FR 26147) (FRL-9945-29) and its supporting documents. Because nothing has changed since the publication of that rule, EPA is incorporating that discussion into this preamble.

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 abamectin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of May 2, 2016 (81 FR 26147) (FRL-9945-29).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to abamectin, EPA considered exposure under the petitioned-for tolerances as well as all existing abamectin tolerances in 40 CFR 180.449. EPA assessed dietary exposures from abamectin 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 abamectin. In estimating acute dietary exposure, EPA used food consumption information from the 2003-2008 United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, a refined acute dietary (food and drinking water) exposure assessment was conducted for all established food uses of abamectin. Acute anticipated residues derived from field trial data were used. Empirical and 2018 DEEM default processing factors and PCT estimates were used, as available. No monitoring data were used.

ii. *Chronic exposure.* The Agency selected a point of departure for chronic effects that is the same as the point of departure for acute effects and so is relying on the acute assessment to be protective of chronic effects. The Agency assessed chronic exposure for purposes of providing background dietary exposure for use in the residential short-term assessments and to incorporate residues/exposure from the food handling establishment (FHE) uses. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 2003-2008 USDA NHANES/WWEIA. As to residue levels in food, a refined chronic dietary (food and drinking water) exposure assessment was conducted for all established food uses of abamectin. Average residues from field trials were used. Residues from use in FHE were included. Empirical and default processing factors and PCT estimates were used, as available.

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

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(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 calls as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section

408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

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

The following maximum PCT estimates for abamectin were used in the acute dietary risk assessment for the following crops: almond: 80%; apple: 30%; apricot: 30%; avocado: 60%; bean, dry: 2.5%; blackberry: 68%; boysenberry: 68%; cantaloupe: 45%; celery: 70%; cherry: 20%; corn, sweet: 57%; cotton: 30%; cucumber: 10%; grape: 35%; grapefruit: 90%; hazelnut: 2.5%; honeydew: 35%; lemon: 55%; lettuce: 45%; loganberry: 68%; nectarine: 20%; onion, bulb: 10%; orange: 70%; peach: 25%; pear: 85%; pecan: 2.5%; pepper: 30%; pistachio: 2.5%; plum/prune: 35%; potato: 20%; pumpkin: 10%; raspberry: 68%; soybean: 11%;

spinach: 45%; squash: 15%; strawberry: 45%; tangerine: 55%; tomato: 25%; walnut: 55%; and watermelon: 15%.

The PCT values that were used to refine the livestock commodities for the acute assessment were based on: sweet corn (57%) for beef, goat, horse, and sheep commodities; and the FHE uses (5%) for hog and poultry meat and meat byproducts.

The following average PCT estimates for abamectin were used in the chronic dietary risk assessment for the following crops: almond: 70%; apple: 10%; apricot: 15%; avocado: 35%; bean, dry: 2.5%; blackberry: 56%; boysenberry: 56%; cantaloupe: 25%; celery: 45%; cherry: 5%; corn, sweet: 45%; cotton: 20%; cucumber: 5%; grape: 15%; grapefruit: 70%; hazelnut: 2.5%; honeydew: 20%; lemon: 40%; lettuce: 20%; loganberry: 56%; nectarine: 20%; onion, bulb: 2.5%; orange: 40%; peach: 10%; pear: 70%; pecan: 1%; pepper: 15%; pistachio: 2.5%; plum/prune: 10%; potato: 5%; pumpkin: 5%; raspberry: 56%; soybeans: 8%; spinach: 25%; squash: 5%; strawberry: 30%; tangerine: 35%; tomato: 10%; walnuts: 25%; and watermelons: 5%.

The PCT values that were used to refine the livestock commodities for the chronic assessment were based on: cotton (20%), soybean (8%), and sweet corn (45%). The PCT for poultry and hog commodities is based on the FHE PCT (5%) since the tolerances for FHE uses result in residues considerably higher than secondary residues from hogs and poultry consuming treated feed.

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 figures for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up 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 abamectin 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 abamectin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of abamectin. 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 Tier I Pesticide Root Zone Model - Ground Water (PRZM-GW) and Tier I Screening Concentration in Ground Water (SCI-GROW) models and the Tier II surface water concentration calculator (SWCC) computer model, the estimated drinking water concentrations (EDWCs) of abamectin for acute exposures are estimated to be 3.76 parts per billion (ppb) for surface water and 0.074 ppb for ground water, and for chronic exposures are estimated to be 1.21 ppb for surface water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the Agency used a residue distribution file for water based upon the maximum single application rate to ornamentals. For the chronic dietary risk assessment, the water concentration of value 1.21 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).

Abamectin is currently registered for the following uses that could result in residential exposures: golf course turf, homeowner bait and bait station products that include an outdoor granular bait formulation for use on fire ant mounds, and several indoor ready-to-use baits of both dust and gel formulations. In addition, there is a pending action for use on professional and collegiate sports fields that has been incorporated into this review.

EPA assessed residential exposure using the following assumptions: For residential handlers, both dermal and inhalation short-term exposure is expected from the currently registered bait and bait station uses. Residential post-application exposure for adults and children (6 to <11 and 11 to <16) is possible for the use of abamectin on golf courses and collegiate and professional sports fields. Adults and children (6 to <11 and 11 to <16) performing physical post-application activities may receive dermal exposure to abamectin residues. For the indoor liquid spray application as a spot or crack and crevice treatment, residential post-application exposures are possible. However, for the outdoor liquid spray application, exposures are expected to be negligible, and therefore, were not quantitatively assessed. Adults and children performing physical post-application activities on carpets and hard surfaces may receive exposure to abamectin residues.

The following residential post application scenarios were used in the aggregate assessment because they result in the lowest MOEs: Adults (dermal) from exposure to collegiate sports field turf; children 11 to less than 16 years old (dermal) from exposure to golf course turf; children 6 to less than 11 years old (dermal) from exposure to golf

course turf; and children 1 to less than 2 years old (dermal, inhalation, and incidental oral) from exposure to carpets.

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 FFDCFA 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 determined that abamectin and emamectin share characteristics to support a testable hypothesis for a common mechanism of action. Following this determination, the Agency conducted a screening-level cumulative risk assessment to determine if cumulative exposures to these chemicals would pose a risk of concern. This screening assessment indicates that that cumulative dietary and residential aggregate exposures for abamectin and emamectin are below the Agency's levels of concern. No further cumulative evaluation is necessary for abamectin and emamectin.

The Agency's screening-level cumulative analysis can be found at <http://www.regulations.gov> in the document titled “*Avermectin Macrocyclic Lactones, Abamectin and Emamectin. Cumulative Screening Risk Assessment*” in docket ID number EPA-HQ-OPP-2018-0037.

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.* An increase in qualitative susceptibility was seen in the rabbit developmental toxicity study, where decreases in body weight and food consumption were seen in maternal animals at 2.0 mg/kg/day. In contrast, the fetal effects were much more severe, consisting of cleft palate, clubbed foot, and death at 2.0 mg/kg/day. The point of departure (0.25 mg/kg/day) selected from the dog studies is 8x lower than the dose where rabbit fetal effects were seen. Therefore, it is protective of fetal effects seen in the rabbit developmental toxicity study.

The rat reproduction toxicity and developmental neurotoxicity studies demonstrated both qualitative and quantitative susceptibility in the pups to the effects of abamectin (decrease pup weights and increased postnatal pup mortality). This observation is consistent with the finding that P-gp is not fully developed in rat pups until postnatal day 28. Therefore, during the period from birth to postnatal day 28, the rat pups are substantially more susceptible to the effects of abamectin than adult rats. However, in humans, P-gp has been detected in the fetus at 22 weeks of pregnancy, and the human

newborns have functioning P-gp. Therefore, human infants and children are not expected to have enhanced sensitivity as seen in rat pups.

3. *Conclusion.* Currently, the toxicity endpoints and points of departure for all exposure scenarios are selected from the subchronic and chronic oral toxicity studies in the dogs. The points of departure selected from the dog studies are based on clear NOAELs and protective of all the adverse effects seen in the studies conducted in human relevant studies with rats, CD-1 mice, and rabbits. Therefore, EPA has determined that 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 abamectin is complete.
- ii. The proposed mode of action (MOA) is interaction with GABA receptors leading to neurotoxicity. The findings of neurotoxic signs observed in the abamectin database are consistent with the proposed MOA. Signs of neurotoxicity ranging from decreases in foot splay reflex, mydriasis (i.e., excessive dilation of the pupil), curvature of the spine, decreased fore- and hind-limb grip strength, tip-toe gate, tremors, ataxia, or spastic movements of the limbs are reported in various studies with different durations of abamectin exposure. In dogs, mydriasis was the most common finding at doses as low as 0.5 mg/kg/day at one week of treatment. No neuropathology was observed. Because the PODs used for assessing aggregate exposure to abamectin and the PODs for assessing cumulative exposure for abamectin and emamectin are protective of these neurotoxic effects in the U.S. population, as well as infants and children, no additional data concerning neurotoxicity is needed at this time to be protective of potential neurotoxic effects.

iii. As explained in Unit III.D.2 “Prenatal and postnatal sensitivity”, the enhanced susceptibility seen in the rabbit developmental toxicity, the rat reproduction, and the rat developmental neurotoxicity studies do not present a risk concern.

iv. There are no residual uncertainties identified in the exposure databases. The chronic and acute dietary food exposure assessment are refined including use of anticipated residues, default processing factors, and percent crop treated; however, these refinements are considered protective because field trials are conducted to represent use conditions leading to the maximum residues in food when the product is used in accordance with the label and do not underestimate exposures. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to abamectin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by abamectin.

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 abamectin will occupy 64%

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 abamectin from food and water will utilize 13% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of abamectin is not expected.

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).

Abamectin 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 abamectin.

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 790 for adults, 2900 for children aged 11 to less than 16 years old, 1800 for children aged 6 to less than 11 years old, and 180 for children 1-2 years old. Because EPA's level of concern for abamectin 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).

Intermediate-term adverse effects were identified; however, abamectin is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no 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 intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for abamectin.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, abamectin 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 abamectin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods for abamectin in plant and livestock commodities are available in the Pesticide Analytical Manual, Volume II (PAM II).

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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for abamectin on either tea or banana.

C. Revisions to Petitioned-For Tolerances

The petitioner proposed a tolerance level of 0.002 ppm for residues in/on banana. The tolerance is being established at the level of the combined limit of quantitation (LOQs) for the residues of concern which is 0.006 ppm. The tolerance level for tea, dried is being established at 1.0 ppm, which alters the proposed tolerance of 1 ppm to adjust for significant figures and commodity definition revision.

V. Conclusion

Therefore, tolerances are established for residues of abamectin, in or on banana at 0.006 ppm and tea, dried at 1.0 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDC 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 tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of 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: February 8, 2019.

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 § 180.449, add alphabetically the entries “Banana” and “Tea, dried” to the table in paragraph (a) to read as follows:

§ 180.449 Avermectin B1 and its delta-8,9-isomer; tolerances for residues.

(a) * * *

Commodity	Parts per million
****	***
Banana ¹	0.006
****	***
Tea, dried ¹	1.0

****	***
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¹There are no U.S. registrations for use of abamectin on banana or tea.

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