ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0428; FRL–9945–29]

Abamectin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of abamectin in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4), Syngenta Crop Protection, and Y–TEX Corporation requested these tolerances in four separate petitions under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 2, 2016. Objections and requests for hearings must be received on or before July 1, 2016, 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–2013–0428, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2013–0428 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 July 1, 2016. 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–2013–0428, 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 Tolerances

In the **Federal Register** of September 12, 2013 (78 FR 56185) (FRL–9399–7), 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 Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W., Princeton, NJ 08540 (PP 3E8175) and Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419 (PP 3F8184). The petitions requested that 40 CFR 180.449 be amended by establishing tolerances for residues of the insecticide avermectin (abamectin) determined by measuring only avermectin B_1, a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-*O*-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1), and its delta-8,9-isomer in or on caneberry subgroup 13–07A at 0.20 parts per million (ppm) (PP 3E8175), and corn, field, sweet, and pop at 0.01 ppm; corn, field and pop, forage at 0.2 ppm; corn, field and pop, grain at 0.01 ppm; corn, field and pop, stover at 0.6 ppm; corn, sweet, forage at 0.2 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, sweet, stover at 0.5 ppm; soybean at 0.01 ppm; soybean, forage at 0.3 ppm; soybean, hay at 1 ppm; and soybean, seed at 0.01 ppm (PP 3F8184). That document referenced summaries of the petitions prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notices of filing.

In the **Federal Register** of February 25, 2014 (79 FR 10458) (FRL–9906–77), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3) announcing the filing of pesticide petition by Y-TEX Corporation, 1825 Big Horn Avenue, P.O. Box 1450, Cody, WY 82414 (PP 3F8200). The petition requested that 40 CFR 180.449 be amended by increasing an established tolerance for the combined residues of the insecticide

avermectin B_1 (a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-O-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-O-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1)) and its delta-8,9-isomer, in or on milk from 0.005 ppm to 0.01 ppm. That document referenced a summary of the petition prepared by Y–TEX Corporation, the registrant, which is available in the docket for docket ID number EPA–HQ–OPP–2013–0264, *http://www.regulations.gov.* There were no FFDCA-related comments received in response to the notice of filing.

In the **Federal Register** of February 11, 2015 (80 FR 7559) (FRL–9921–94), 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 by IR–4, 500 College Road East, Suite 201 W., Princeton, NJ 08540 (PP 4E8309). The petition requested that 40 CFR 180.449 be amended by establishing tolerances for residues of the insecticide avermectin (abamectin) determined by measuring only avermectin B_1, a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-*O*-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1), and its delta-8,9-isomer in or on fruit, stone, group 12–12 at 0.09 ppm, fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.02 ppm, nut, tree, group 14–12 at 0.01 ppm, vegetable, fruiting, group 8–10 at 0.07 ppm, fruit, citrus, group 10–10 at 0.02 ppm, berry, low growing, subgroup 13–07G at 0.05 ppm, fruit, pome, group 11–10 at 0.02 ppm, papaya at 0.40 ppm, star apple at 0.40 ppm, black sapote at 0.40 ppm, sapodilla at 0.40 ppm, canistel at 0.40 ppm, mamey sapote at 0.40 ppm, guava at 0.015 ppm, feijoa at 0.015 ppm, jaboticaba at 0.015 ppm, wax jambu at 0.015 ppm, starfruit at 0.015 ppm, passionfruit at 0.015 ppm, acerola at 0.015 ppm, lychee 0.01 ppm, longan at 0.01 ppm, Spanish lime at 0.01 ppm, rambutan at 0.01 ppm, pulasan at 0.01 ppm, pineapple at 0.015 ppm, bean at 0.015 ppm, and onion, green, subgroup 3–07B at 0.08 ppm. Upon the approval of the aforementioned tolerances, IR–4 requested removal of established tolerances of abamectin, including its metabolites and degradates, in or on the following commodities: Bean, dry, seed at 0.01 ppm, citrus at 0.02 ppm, apple at 0.02 ppm, pear at 0.02 ppm, fruit, stone, group 12 at 0.09 ppm, nut, tree, group 14 at 0.01 ppm, pistachio at 0.01 ppm, grape at 0.02 ppm, strawberry at 0.05 ppm and vegetable, fruiting, group 8 at 0.02 ppm. That document referenced summaries of the petitions prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions, EPA has modified the level at which tolerances are being established for some commodities. The reasons 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.

Abamectin is a mixture of avermectin B_1 [a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-*O*-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1)] and its delta-8,9-isomer. Avermectins are macrocyclic lactones produced as natural fermentation products of the soil bacterium *Streptomyces avermitilis.* Currently, abamectin and emamectin are the only members of this group with active pesticide registrations. The two components of abamectin, B_{1a} and B_{1b}, have very similar biological and toxicological properties. Emamectin, which is a derivative of abamectin, is a structurally and toxicologically related chemical. The only difference between abamectin and emamectin is that abamectin has a hydroxyl moiety at the 4″ position of the tetrahydropyrane ring, whereas in emamectin the hydroxyl group is replaced by a methylamine.

Since the last time the EPA assessed abamectin (**Federal Register** of March 27, 2013 (78 FR 18519) (FRL–9379–1)), the Agency has re-evaluated the entire abamectin and emamectin toxicological database along with currently available literature information on the toxicity of the abamectin and emamectin to ensure consistent hazard evaluation for these structurally related pesticides. This hazard characterization and dose-response assessment represents a more refined analysis than previous assessments, using the literature data to enhance the characterization of the studies submitted to the Agency.

Available toxicity data show that, with single dose or repeated dose administration, the primary target organ of abamectin is the nervous system, and that decreased body weight is also one of the most frequent findings. Neurotoxicity (including tremors, mydriasis, ataxia, and death) was seen in mice, dogs, and rats. Developmental effects such as cleft palate were reported in rabbits. Abamectin was shown to bind to the gamma aminobutyric acid (GABA) receptors, and this interaction was believed to result in neurotoxicity. The GABA receptor interaction also plays a role in development; cleft palate findings may reflect the interaction of abamectin on the GABA receptor. Generally the finding of cleft palate was seen at higher dose levels than those for neurotoxicity.

Integral to the dose response assessment in mammals for this class of compounds is P-glycoprotein (P-gp). P-gp is a member of adenosine triphosphate (ATP) binding cassette transporter proteins, which reside in the plasma membrane and function as a transmembrane efflux pump, moving

xenobiotics from the intracellular to the extracellular domain. P-gp is found in the canallicular surface of hepatocytes, the apical surface of proximal tubular cells in the kidneys, the brush border surface of enterocytes, and the luminal surface of blood capillaries of the brain (blood brain barrier), placenta, ovaries, and the testes. As an efflux transporter, P-gp acts as a protective barrier to keep xenobiotics out of the body by excreting them into bile, urine, and intestinal lumen and prevents accumulation of these compounds in the brain and gonads, as well as in the fetus. Therefore, test animals with genetic polymorphisms that compromise P-gp expression, are particularly susceptible to abamectin-induced neurotoxicity (Lankas et al., 1997). An example is the rat. P-gp is undetectable in the neonatal rat brain; the first detection of P-gp is on post-natal day (PND) 7 and does not reach adult levels until approximately PND 28 (Matsuoka, 1999). As shown in the reproductive and developmental neurotoxicity (DNT) studies, neonatal rats are sensitive to the effects of abamectin-induced pup body weight reductions and death. In contrast, in the developing human fetus, P-gp was found as early as 22 weeks of gestation (Daood, MJ, 2008; van Kalken, et al., 1991). Based on the difference in the ontogeny of P-gp in neonatal rat and human newborn, the Agency, at this time, does not believe that the early post-natal findings in the rat to be relevant to human newborns or young children.

Similarly, the CF-1 mouse is also uniquely sensitive to the neurotoxic effects of abamectin and its derivative, emamectin. Some CF-1 mice have a polymorphism for the gene encoding P-gp and are either devoid (homozygous) or have diminished (heterozygous) level of P-gp. The Agency does not consider the results of studies with CF-1 mice to be relevant for human health risk assessment because there is a lack of convincing evidence from the literature on human polymorphism of human multidrug resistance (*MDR-1*) gene resulting in diminished P-gp function. Although many studies on human multidrug resistance (*MDR-1*) gene encoding P-gp and polymorphism of *MDR-1* gene are available, the data are inconclusive with respect to the functional significance of the genetic variance in P-gp in human. At the present, the reported cases of polymorphism of the *MDR-1* gene in human populations have not been shown to result in a loss of P-gp function similar to that found in CF-1 mice (Macdonald & Gledhill, 2007). As a result, the Agency does not consider the toxic effects observed in CF-1 mouse studies to be representative of abamectin (and emamectin) effects in humans.

Therefore, the Agency is using results from toxicological studies conducted in the species (rats, CD-1 mice, rabbits, and dogs) that do not have diminished P-gp function for selecting toxicity endpoints and points of departure for risk assessment. Among the test animals with fully functional P-gp, the beagle dog is the most sensitive species.

For various durations of treatment (subchronic (12- and 18-weeks) and chronic oral toxicity studies in dogs), clinical signs [tremors and mydriasis (decreased pupillary light response)] of neurotoxicity were observed in the at the lowest observed adverse effect level (LOAEL) of 0.5 milligram/kilogram (mg/kg); the no observed adverse effect level (NOAEL) was 0.25 mg/kg. Tremors and mydriasis were observed as early as the first week of exposure. The Agency assumes that these clinical signs could result from a single dose for the following reasons:

1. Kinetic data demonstrates rapid absorption/excretion. With oral dosing in rats and mice, abamectin was absorbed rapidly, and maximum concentration in blood was achieved within 4-8 hours after administration. It was rapidly eliminated from the body, almost exclusively in the feces, and did not accumulate in the body after repeated exposure.

2. In an acute neurotoxicity study (ACN) in rat (range finding and main studies), clinical signs of neurotoxicity such as reduced foot splay reflex, ataxia, tremors, and mydriasis (decreased pupillary light response) were observed from a single dose. Most of the effects observed in the rat ACN were consistent with those seen in the subchronic and chronic dog studies.

3. The neurotoxic effects produced by abamectin in beagle dogs did not progress with time. The effects seen in the subchronic (gavage) and chronic dog studies were similar despite the varied durations of treatment, suggesting the response could be due to each individual exposure rather than to accumulation of abamectin in tissues. Clinical signs such as ataxia and or whole body tremors were reported within 3 hours of the first dose at higher dose levels.

Based on these considerations, 0.25 mg/kg/day was selected as a point of departure for risk assessment for all the exposure scenarios, and the toxicity endpoints were clinical signs of neurotoxicity.

Carcinogenicity studies in rats and mice (CD-1) and mutagenicity studies provide no indication that abamectin is carcinogenic or mutagenic.

Specific information on the studies received and the nature of the adverse effects caused by abamectin 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 ''*Abamectin. Human Health Risk Assessment for Uses on Caneberry Subgroup 13–07A; Soybean; Sweet Corn; Ear Tags for Lactating Dairy Cattle; Golf Course Turf; Bean; Onion, Green, Subgroup 3–07B; Fruit, Pome, Group 11–10; Fruit, Small Vine Climbing, Except Fuzzy Kiwifruit, Subgroup 13–07F; Berry, Low Growing, Subgroup 13–07G; Vegetable, Fruiting, Group 8–10; Greenhouse Tomato; Fruit, Citrus, Group 10–10; Fruit, Stone, Group 12–12; and Nut, Tree, Group 14–12; and Various Tropical Fruits''* on page 53 in docket ID number EPA–HQ–OPP–2013–0428.

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 shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ABAMECTIN 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 and Chronic dietary (All populations).	NOAEL = 0.25 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.0025 mg/kg/day. aPAD = 0.0025 mg/kg/day Chronic RfD = 0.0025 mg/kg/day cPAD = 0.0025 mg/kg/day	Subchronic & chronic oral toxicity studies in dogs. Chronic LOAEL = 0.50 mg/kg/day based on body tremors, one death, liver pathology, decreased body weight. Mydriasis was seen during week one in one dog. Subchronic LOAEL = 0.5 mg/kg/day based on mydriasis during week one, death at 1.0 mg/kg/day.
Dermal short-term (1 to 30 days).	Oral study NOAEL = 0.25 mg/kg/day (dermal absorption rate = 1%. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic & chronic oral toxicity studies in dogs. Chronic LOAEL = 0.50 mg/kg/day based on body tremors, one death, liver pathology, decreased body weight. Mydriasis was seen during week one in one dog. Subchronic LOAEL = 0.5 mg/kg/day based on mydriasis during week one, death at 1.0 mg/kg/day.
Inhalation short-term (1 to 30 days).	Oral study NOAEL = 0.25 mg/kg/day (Toxicity via the inhalation route assumed to be equivalent) to oral route. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic & chronic oral toxicity studies in dogs. Chronic LOAEL = 0.50 mg/kg/day based on body tremors, one death, liver pathology, decreased body weight. Mydriasis was seen during week one in one dog. Subchronic LOAEL = 0.5 mg/kg/day based on mydriasis during week one, death at 1.0 mg/kg/day.
Cancer (Oral, dermal, inhalation).	Classification: ''Not likely to be Carcinogenic to Humans'' based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

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).

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 exposure assessment was conducted for all proposed and established food uses of abamectin. Anticipated residues derived from field trial data for most plant commodities were used in the acute dietary exposure assessment. Tolerance-level residues were used for poultry and swine livestock commodities. Because cattle may be exposed to residues of abamectin through diet and ear tag, upper-bound anticipated residues were estimated from the maximum values found in cattle feeding studies and dermal magnitude of residue studies. For all other livestock commodities, upper-bound anticipated residues were estimated from secondary residues from consuming treated feed. Empirical and default processing factors and maximum percent crop treated (PCT) estimates were used, as available.

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. So, the Agency assessed chronic exposure for purposes of providing background dietary exposure for use in the residential short-term assessments. 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 exposure assessment was conducted for all proposed and established food uses of abamectin. Average residues for plant commodities from field trials were used. Residue levels based on maximum reasonable dietary burden for secondary residues in livestock (beef and dairy cattle) and the highest residues found in the magnitude of residue studies for cattle ear tags were used in the chronic assessment for livestock commodities. Tolerance values were used for poultry and swine to account for poultry and swine consuming treated feed. Residues from use in food handling establishments were included. Empirical and default processing factors and average 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 PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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

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

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

The following maximum PCT estimates were used in the acute dietary risk assessment for the following crops that are currently registered for abamectin: Almond: 80%; apple: 30%; apricot: 30%; avocado: 60%; bean, dry: 2.5%; cantaloupe: 45%; celery: 70%; cherry: 20%; cotton: 30%; cucumber: 10%; grape: 35%; grapefruit: 90%; hazelnut: 2.5%; honeydew: 35%; lemon: 55%; lettuce: 45%; 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%; 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 (44%) for beef, goat, horse, and sheep commodities; and the food handling establishment uses (5%) for hog and poultry meat and meat byproducts.

The following average PCT estimates were used in the chronic dietary risk assessment for the following crops that are currently registered for abamectin: Almond: 70%; apple: 10%; apricot: 15%; avocado: 35%; bean, dry: 2.5%; cantaloupe: 25%; celery: 45%; cherry: 5%; cotton: 20%; cucumber: 5%; grape: 15%; grapefruit: 70%; hazelnut: 2.5%; honeydew: 20%; lemon: 40%; lettuce: 20%; 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%; 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 (cattle, goats, horses, and sheep) for the chronic assessment were based on: Cotton (30%), soybean (8%), and sweet corn (38%). The PCT for poultry and hog commodities is based on the food handling establishment PCT since the tolerances for food handling establishment uses result in residues considerably higher than secondary residues from hogs and poultry consuming treated feed. All commodities included for food handling residues were assigned the value of 5%.

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

The following maximum PCT estimates were used in the acute dietary risk assessment for the following new uses of abamectin:

Blackberries: 68%; boysenberry: 68%; corn, sweet 57%; loganberry: 68%; raspberries: 68%; soybeans: 11%.

The following average PCT estimates were used in the chronic dietary risk assessment for the following new uses of abamectin:

Blackberries: 56%; boysenberry: 56%; corn, sweet 45%; loganberry: 68%; raspberries: 56%; soybeans: 8%.

EPA estimates of the PCTn of abamectin represents the upper bound of use expected during the pesticide's initial five years of registration; that is, PCTn for abamectin is a threshold of use that EPA is reasonably certain will not be exceeded for each registered use site. The PCTn 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 PCTn 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 PCTn 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 PCTn for abamectin could be exceeded, EPA considered whether there may be unusually high pest pressure, as indicated in emergency exemption requests for abamectin; 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 abamectin with significant market potential. Given

currently available information, EPA concludes that it is unlikely that actual PCT for abamectin will exceed the estimated PCT for new uses during the next five 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 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 II surface water concentration calculator (SWCC) computer model and Tier I Screening Concentration in Ground Water (SCI–GROW) model and Tier I Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of abamectin for acute exposures are estimated to be 0.76 parts per billion (ppb) for surface water and 0.074 ppb for ground water and for chronic exposures are estimated to be 0.30 ppb for surface water and ≤0.0031 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model either via point estimates or using residue distribution files.

For acute dietary risk assessment, a drinking water residue distribution file was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 0.30 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: 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, as part of the current request, the registrant has proposed a use on golf course turf.

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. Quantitative exposure/risk assessment considered the following scenarios: Loading/applying granular bait outdoor via (1) push-type spreaders, (2) belly grinders, (3) spoons, (4) hand, and (5) cup or shaker; and (6) applying granular bait indoor by hand (as a surrogate for a ready-to-use dust bait).

Post-application residential exposure for adults and children (1 to <2) is unlikely for the currently registered uses of abamectin. For currently registered outdoor treatments, adults and children are not expected to directly contact fire ant mounds. For currently registered indoor pest control, bait placements are intended to be placed in cracks and crevices where direct contact by adults and children (1 to <2) is unlikely.

However, residential post-application exposure for adults and children (6 to <11 and 11 to <16) is possible for the newly proposed use of abamectin on golf courses. Adults and children (6 to <11 and 11 to <16) performing physical post-application activities on golf course turf may receive dermal exposure to abamectin residues. The scenarios, lifestages, and routes of exposure include: Golfing for adults (dermal), children 11 to <16 years old (dermal), and children 6 to <11 years old (dermal).

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's Office of Pesticide Programs (OPP) has previously developed guidance documents for establishing common mechanism groups (CMGs) (*Guidance for Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (1999)) and conducting cumulative risk assessments (CRAs) (*Guidance on Cumulative Risk Assessment of Pesticide Chemicals that have a Common Mechanism of Toxicity* (2002)). In 2016, EPA's Office of Pesticide Programs released another guidance document entitled *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis.* All three of these documents can be found at *http://www.regulations.gov* in docket ID EPA–HQ–OPP–2015–0422.

The Agency has utilized this 2016 screening framework for abamectin and determined that abamectin along with emamectin form a candidate CMG. This group of pesticides is considered a candidate CMG because they 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 consistent with the 2016 guidance document. 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 ''*Abamectin. Human Health Risk Assessment for Uses on Caneberry Subgroup 13–07A; Soybean; Sweet Corn; Ear Tags for Lactating Dairy Cattle; Golf Course Turf; Bean; Onion, Green, Subgroup 3–07B; Fruit, Pome, Group 11–10; Fruit, Small Vine Climbing, Except Fuzzy Kiwifruit, Subgroup 13–07F; Berry, Low Growing, Subgroup 13–07G; Vegetable, Fruiting, Group 8–10; Greenhouse Tomato; Fruit, Citrus, Group 10–10; Fruit, Stone, Group*

12–12; and Nut, Tree, Group 14–12; and Various Tropical Fruits'' on page 74 (Appendix H) in docket ID number EPA–HQ–OPP–2013–0428.

Additionally, when the Agency issued the notice in the **Federal Register** announcing the availability of the draft framework guidance, the EPA also received comments on the draft human health risk assessment for abamectin, which was included in that docket as an example of how EPA would implement the draft framework guidance. The response to those comments can be found in docket ID number EPA–HQ–OPP–2013–0428.

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 Food Quality Protection Act (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 more than 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 88% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions discussed in this unit for chronic exposure, the chronic dietary exposure from food and water to abamectin will occupy 11% of the cPAD for children 1–2 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 4,400 for adults, 3,600 for children 11 to <16 years old, and 2,100 for children 6 to <11 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).

An intermediate-term adverse effect was 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 the acute dietary risk assessment is protective of all exposure durations (since the point of departure is the same for all exposure durations), no further assessment of intermediate-term risk is necessary.

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 FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for abamectin on sweet corn, soybean, papaya, star apple, black sapote, sapodilla, canistel, mamey sapote, guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, acerola, lychee, longan, Spanish lime, rambutan, pulasan, pineapple, bean or green onion commodities. Additionally, there are no Codex MRLs for abamectin on the commodities in the caneberry subgroup 13–07A; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F; or fruit, stone, group 12–12.

The following U.S. tolerances are harmonized with established, related Codex MRLs: Fruit, pome, group 11–10; and nut, tree, group 14–12.

The Codex MRL on citrus is not harmonized with the U.S. tolerance on fruit, citrus, group 10–10, and the Codex MRL on strawberry is not harmonized with the recommended U.S. tolerance on berry, low-growing, subgroup 13–07G. Residue data underlying these U.S. tolerances supports tolerances that are higher than the established Codex MRLs on these related commodities.

Codex MRLs for abamectin on fruiting vegetable commodities are not harmonized with the U.S. tolerance on vegetable, fruiting, group 8–10. The residue data underlying the U.S. fruiting vegetable tolerance resulted in a tolerance that is higher than the established Codex MRL on sweet peppers. Codex has also established a separate tolerance on dried chili pepper that is higher than the U.S. fruiting vegetable tolerance.

There are some Codex MRLs on livestock commodities, but none of the Codex MRLs are set at the same level as the tolerance levels EPA is establishing today; however, the U.S. cannot harmonize with the Codex MRLs on livestock commodities since the Codex MRLs reflect different uses (*i.e.,* different dietary burdens) as compared to the uses in the United States, which also reflect the direct treatment of cattle via ear tags. Setting U.S. tolerances at Codex MRL levels would result in tolerance violations for some livestock commodities.

C. Revisions to Petitioned-For Tolerances

Although not requested, EPA is establishing a tolerance of 0.40 ppm for ''grain, aspirated grain fractions'' since aspirated grain fractions are associated with soybeans. The recommended tolerance of 0.40 ppm for ''grain, aspirated grain fractions'' is based on residues of <0.006 ppm in soybean seed and a concentration factor of 59X in aspirated grain fractions.

EPA is also increasing some of the established livestock tolerances based on a new dietary burden calculation that includes the proposed uses on soybeans and sweet corn as well as a proposed use for ear tags for lactating dairy cattle. Because of these calculations, EPA is increasing the established tolerances on cattle fat from 0.03 to 0.05 ppm; cattle meat byproducts from 0.06 to 0.09 ppm; fat of goat, horse and sheep from 0.01 to 0.03 ppm; meat byproducts of goat, horse, and sheep from 0.02 to 0.04 ppm; and milk from 0.005 to 0.015 ppm.

Finally, EPA is not establishing tolerances for ''corn, field, sweet, and pop; corn, field and pop, forage; corn, field and pop, grain; corn, field and pop, stover'' because the petitioner withdrew those tolerance requests.

D. Literature References

Daood., MJ, Tsai, C., Ahdab-Barmada, M., and Watchko, JF (2008). ABC transporter (P-gp/ABCB1, MRP1/ABCC1, BCRP/ABCG2) expression in the developing Human CNS. *Neuropediatrics.* 2008 August; 39(4): 211.

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Macdonald, N. and Gledhill, A. (2007). Potential impact of ABCB1 (p-glycoprotein) polymorphisms on avermectin toxicity in human. *Arch Toxicol* (2007) 81:553–563.

Matsukoa, Y., Okazaki, M., Kitamura, Y., and Taniguchi, T. (1999). Developmental expression of P-glycoprotein (multidrug resistance gene product) in the rat brain. *Journal of Neurobiology,* 39(3), 383–392.

van Kalken, CK, Giaccone, G., van der Valk, P., Kuiper, CM, Hadisaputro, MMN, Bosma, SAA, Scheper, RJ, Meijer, CJLM, and Pinedo, HM (1992). Multidrug resistance gene (P-glycoprotein) expression in the human fetus. *American Journal of Pathology,* vol 141 No.5, November 1992.

V. Conclusion

Therefore, tolerances are established for residues of abamectin in or on acerola at 0.015 ppm; bean at 0.015 ppm; berry, low growing, subgroup 13–07G at 0.05 ppm; black sapote at 0.40 ppm; caneberry subgroup 13–07A at 0.20 ppm; canistel at 0.40 ppm; corn, sweet, forage at 0.20 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, sweet, stover at 0.50 ppm; feijoa at 0.015 ppm; fruit, citrus, group 10–10 at 0.02 ppm; fruit, pome, group 11–10 at 0.02 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F 0.02 ppm; fruit, stone, group 12–12 at 0.09 ppm; grain, aspirated grain fractions at 0.40 ppm; guava at 0.015 ppm; jaboticaba at 0.015 ppm; longan at 0.01 ppm; lychee at 0.01 ppm; mamey sapote at 0.40 ppm; nut,

tree, group 14–12 at 0.01 ppm; onion, green, subgroup 3–07B at 0.08 ppm; papaya at 0.40 ppm; passionfruit at 0.015 ppm; pineapple at 0.015 ppm; pulasan at 0.01 ppm; rambutan at 0.01 ppm; sapodilla at 0.40 ppm; soybean, forage at 0.30 ppm; soybean, hay at 1.0 ppm; soybean, seed at 0.01 ppm; Spanish lime at 0.01 ppm; star apple at 0.40 ppm; starfruit at 0.015 ppm; vegetable, fruiting, group 8–10 at 0.07 ppm; and wax jambu at 0.015 ppm.

In addition, EPA is increasing the established tolerances on cattle, fat from 0.03 to 0.05 ppm; cattle, meat byproducts from 0.06 to 0.09 ppm; fat of goat, horse, and sheep from 0.01 to 0.03 ppm; meat byproducts of goat, horse, and sheep from 0.02 to 0.04 ppm; and milk from 0.005 to 0.015 ppm.

And lastly EPA is removing the following tolerances as unnecessary due to the establishment of the aforementioned tolerances: Apple at 0.02 ppm; bean, dry, seed at 0.01 ppm; citrus at 0.02 ppm; fruit, stone, group 12 at 0.09 ppm; grape at 0.02 ppm; nut, tree, group 14 at 0.01 ppm; pear at 0.02 ppm; pistachio at 0.01 ppm; strawberry at 0.05 ppm; and vegetable, fruiting, group 8 at 0.020 ppm.

VI. Statutory and Executive Order Reviews

This action 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 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). 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: April 22, 2016.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.449, the table in paragraph (a) is revised to read as follows:

§ 180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

(a) * * *

Commodity	Parts per million
Acerola	0.015
Almond, hulls	0.10
Apple, wet pomace	0.10
Avocado	0.020
Bean	0.015
Berry, low growing, subgroup 13–07G	0.05
Black sapote	0.40
Caneberry subgroup 13–07A	0.20
Canistel	0.40
Cattle, fat	0.05
Cattle, meat	0.02
Cattle, meat byproducts	0.09
Celeriac, roots	0.05
Celeriac, tops	0.05
Chive, dried leaves	0.02
Chive, fresh leaves	0.01
Citrus, dried pulp	0.10

Commodity	Parts per million
Citrus, oil	0.10
Corn, sweet, forage	0.20
Corn, sweet, kernel plus cob with husk removed	0.01
Corn, sweet, stover	0.50
Cotton, gin byproducts	1.0
Cotton, undelinted seed	0.02
Feijoa	0.015
Food products in food handling establishments (other than those already covered by higher tolerances as a result of use on growing crops, and other than those already covered by tolerances on milk, meat, and meat byproducts)	0.01
Fruit, citrus, group 10–10	0.02
Fruit, pome, group 11–10	0.02
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.02
Fruit, stone, group 12–12	0.09
Goat, fat	0.03
Goat, meat	0.02
Goat, meat byproducts	0.04
Grain, aspirated grain fractions	0.40
Guava	0.015
Herb subgroup 19A, except chive	0.030
Hog, fat	0.01
Hog, meat	0.02
Hog, meat byproducts	0.02
Hop, dried cones	0.20
Horse, fat	0.03
Horse, meat	0.02
Horse, meat byproducts	0.04
Jaboticaba	0.015
Longan	0.01
Lychee	0.01
Mamey sapote	0.40
Milk	0.015
Nut, tree, group 14–12	0.01
Onion, bulb, subgroup 3–07A	0.01
Onion, green, subgroup 3–07B	0.08
Papaya	0.40
Passionfruit	0.015
Peppermint, tops	0.010
Pineapple	0.015
Plum, prune, dried	0.025
Poultry, meat	0.02
Poultry, meat byproducts	0.02
Pulasan	0.01
Rambutan	0.01
Sapodilla	0.40
Sheep, fat	0.03
Sheep, meat	0.02
Sheep, meat byproducts	0.04
Soybean, forage	0.30
Soybean, hay	1.0
Soybean, seed	0.01
Spanish lime	0.01
Spearmint, tops	0.010
Star apple	0.40
Starfruit	0.015
Vegetable, cucurbit, group 9	0.005
Vegetable, fruiting, group 8–10	0.07
Vegetable, leafy, except brassica, group 4	0.10
Vegetable, tuberous and corm, subgroup 01C	0.01
Wax jambu	0.015

* * * * *

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