BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0619; FRL-8890-2]

Abamectin (avermectin); Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of abamectin (avermectin) in or on onion, bulb, subgroup 3-07A; chive, fresh leaves; chive, dried leaves; and bean, dry, seed. This regulation additionally removes time-limited tolerances on bean, lima, seed; and onion, bulb, as the tolerances will be superseded by permanent tolerance. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0619. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in

hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; e-mail address: *nollen.laura@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification

System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0619 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 that does not contain any 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 a copy of

your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0619, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 11, 2010 (75 FR 48667) (FRL-8840-6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E7738) by IR-4, 500 College Rd. East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.449 be amended by establishing tolerances for residues of the insecticide abamectin (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 bean, dry, seed at 0.01 parts per million (ppm); chive, dried leaves at 0.07 ppm; chive,

fresh leaves at 0.01 ppm; and onion, bulb, subgroup 3-07A at 0.01 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance for chive, dried leaves. Additionally, the Agency has revised the tolerance expression for all established commodities to be consistent with current Agency policy. 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA**,** 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 (avermectin) including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with abamectin (avermectin) 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 (avermectin) has moderate to high acute toxicity by the oral route, high acute toxicity by the inhalation route, and low acute toxicity by the dermal route. It is slightly irritating to the skin, but is not an ocular irritant or a dermal sensitizer. The main target organ for abamectin (avermectin) is the nervous system. Neurotoxicity and developmental effects were detected in multiple studies and species of test animals. Signs of neurotoxicity were reported in studies of rats, mice, and dog and included decreases in foot splay reflex, mydriasis, curvature of the spine, decreased fore- and hind-limb grip strength, tip-toe gate, tremors, ataxia, or spastic movements of the limbs. Decreased body weight was also one of the most frequent findings. Severe effects, including death and morbid sacrifice, were noted in studies with rats and mice following repeated exposures.

Increased qualitative and/or quantitative susceptibility was seen in prenatal developmental toxicity studies in mice and rabbits, and the reproductive toxicity and

developmental neurotoxicity studies in rats. Developmental data indicate that the most sensitive effect of abamectin (avermectin) on fetuses is the increase in the incidence of cleft palates in mice and rabbits in the presence of no or minimal maternal toxicity. No maternal or developmental toxicity was seen in the prenatal developmental toxicity study in rats.

The rat reproductive toxicity studies (two 1-generation reproduction studies and a 2-generation reproduction study) noted decreased pup body weights and/or survival at lower dose levels than those that caused parental toxicity. The developmental neurotoxicity studies in rats noted pup mortality and/or decreased body weights in the absence of maternal toxicity; there were no signs of neurotoxicity noted. In both the rat reproduction and a developmental neurotoxicity study, the data clearly indicated that the decrease in pup body weight seen at one dose level rapidly progressed to death at the next higher tested dose level. Oncogenicity and mutagenicity studies provide no indication that abamectin (avermectin) is carcinogenic or mutagenic; abamection (avermectin) has been classified as "not likely to be carcinogenic to humans."

Specific information on the studies received and the nature of the adverse effects caused by abamectin (avermectin) 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 document: "**Abamectin.** Human Health Risk Assessment for Proposed Uses on the Bulb Onion Subgroup 3-07A, Chives, and Dry Beans," pp. 54-58 in docket ID number EPA-HQ-OPP-2010-0619.

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 the NOAEL and the LOAEL. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for abamectin (avermectin) used for human risk assessment is shown in Table 1 of this unit.

Table 1.—Summary of Toxicological Doses and Endpoints for Abamectin (Avermectin) 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 (General population including infants and children)	NOAEL = 0.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.005 mg/kg/day aPAD = 0.005 mg/kg/day	12-Week dose-range finding study in dogs LOAEL = 1.0 mg/kg/day based on mydriasis seen 1-5 times during the first week of treatment; Acute neurotoxicity study in rats LOAEL= 1.5 mg/kg/day based on increased incidence of foot splay.
Chronic dietary (All populations)	NOAEL= 0.12 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 3x	Chronic RfD = 0.0012 mg/kg/day cPAD = 0.0004 mg/kg/day	Combined data: three rat reproduction studies and two rat developmental neurotoxicity studies LOAEL = 0.2 mg/kg/day based on decreased pup body weight in pups at 0.2 mg/kg/day.
Incidental oral short- and intermediate-term (1 to 30 days and 1 to 6 months)	NOAEL= 0.12 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 3x	LOC for MOE = 300	Combined data: Three rat reproduction studies and two rat developmental neurotoxicity studies LOAEL = 0.2 mg/kg/day based on decreased pup body weight.
Dermal (all durations)	Dermal (or oral) study NOAEL = 0.12 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 3x	LOC for MOE = 300	Combined data: Three rat reproduction studies and two rat developmental neurotoxicity studies LOAEL = 0.2 mg/kg/day based on decreased pup body weight.

Inhalation (all durations)	Dermal (or oral) study NOAEL = 0.12 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 3x	LOC for MOE = 300	Combined data: Three rat reproduction studies and two rat developmental neurotoxicity studies LOAEL = 0.2 mg/kg/day based on decreased pup body weight.
Cancer (Oral, dermal, inhalation)	"Not likely to be carcinogenic to humans" based on the absence of significant increase in tumor incidence in two adequate rodent carcinogenicity studies.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to abamectin (avermectin), EPA considered exposure under the petitioned-for tolerances as well as all existing abamectin (avermectin) tolerances in 40 CFR 180.449. EPA assessed dietary exposures from abamectin (avermectin) 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 (avermectin). In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA utilized tolerance level residues for the proposed crops and okra and anticipated residues for the remaining commodities. Empirical processing factors and percent crop treated (PCT) data were also used, when available.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA utilized tolerance level residues for the proposed crops and okra, and average residues from field trials for the remaining crops. Empirical processing factors and PCT were also used, when available.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that abamectin (avermectin) 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.

For the acute dietary assessment, the maximum PCT for existing uses were estimated as follows:

Almonds, 75%; apples, 10%; apricots, 5%; avocados, 60%; cantaloupes, 30%; celery, 65%; cherries, 2.5%; cotton, 20%; cucumbers, 10%; grapefruit, 80%; grapes, 25%; honeydew, 35%; lemons, 55%; lettuce, 20%; oranges, 45%; peaches, 2.5%; pears, 80%; pecans, 2.5%; peppers, 25%; potatoes, 2.5%; prunes, 10%; pumpkins, 10%; spinach, 45%; squash, 10%; strawberries, 45%; tangerines, 65%; tomatoes, 20%; walnuts, 20%; and watermelons, 10%.

For the chronic dietary assessment, the average PCT for existing uses were estimated as follows:

Almonds, 50%; apples, 5%; apricots, 5%; avocados, 40%; cantaloupes, 15%; celery, 40%; cherries, 1%; cotton, 5%; cucumbers, 5%; grapefruit, 60%; grapes, 10%; honeydew, 20%; lemons, 35%; lettuce, 10%; oranges, 25%; peaches, 1%; pears, 70%; pecans, 1%; peppers, 10%; potatoes, 1%; prunes, 2.5%; pumpkins, 2.5%; spinach, 20%;

squash, 5%; strawberries, 30%; tangerines, 60%; tomatoes, 10%; walnuts, 10%; and watermelons, 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 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 (avermectin) 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 (avermectin) in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of abamectin (avermectin). Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of abamectin (avermectin) for acute exposures are estimated to be 2.3 parts per billion (ppb) for surface water and 1.6 x 10^{-3} ppb for ground water, and for chronic exposures for non-cancer assessments are estimated to be 1.3 ppb for surface water and 1.6 x 10^{-3} ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 2.3 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 1.3 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 (avermectin) is currently registered for the following uses that could result in residential handler and postapplication exposures: Granular baits used to treat lawns and indoor crack and crevice dust products. EPA assessed residential exposure using the following assumptions: Adults were assessed for short- and intermediate-term residential handler and postapplication exposures (dermal and inhalation). Children were assessed for short- and intermediate-term postapplication dermal, inhalation, and incidental ingestion exposures (hand-to-mouth and object-to-mouth). Recreational exposures to turf are expected to be similar to, or less than, those described above, and were therefore not assessed. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found abamectin (avermectin) to share a common mechanism of toxicity with any other substances, and abamectin (avermectin) does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that abamectin (avermectin) does not have a common mechanism of toxicity with other substances. For

information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The abamectin (avermectin) toxicity database is adequate to evaluate potential increased susceptibility of infants and children, and includes developmental toxicity studies in rat, mice, and rabbits; two 1-generation rat reproductive toxicity studies in rat; a 2-generation reproductive toxicity study in rat; and two developmental neurotoxicity studies in rat. No developmental effects were seen in the rat developmental toxicity study. However, increased quantitative susceptibility was noted in the prenatal developmental toxicity studies in mice and rabbits, the rat reproductive toxicity studies, and the developmental neurotoxicity studies in rat.

3. *Conclusion*. In previous abamectin (avermectin) risk assessments, the 10x FQPA safety factor was retained as a database uncertainty factor for the lack of a

developmental neurotoxicity study. Two developmental neurotoxicity studies have now been submitted and reviewed and the findings in these studies were considered in the identification of toxicological points of departure and uncertainty/safety factors.

EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for the acute dietary assessment and 3X for all assessments other than acute dietary. That decision is based on the following findings:

i. For all risk assessments involving repeated exposures to abamectin (avermectin), EPA determined that a 3x safety factor would be appropriate, based on the severity of effects (decrease in pup body weight and mortality) and the steepness of the dose-response curve seen in the developmental neurotoxicity study and three reproductive toxicity studies in the rat. These studies have documented a very narrow dose range from NOAEL (0.12 mg/kg/day) to adverse effect (0.2 mg/kg/day) to severe adverse effect (0.4 mg/kg/day). Dose spacing is commonly greater than 2x between NOAEL and LOAEL, and the 3x difference between the NOAEL and the dose that induced mortality in the pups in the developmental neurotoxicity study provides little margin of safety for the severity of the effects seen.

Retaining an additional 3x FQPA safety factor effectively provides a 10x margin between the dose which causes death (0.4 mg/kg/day) and the NOAEL adjusted by the additional safety factor (0.12 mg/kg/day /3x = 0.04 mg/kg/day). A dose spacing of 10x between a NOAEL and LOAEL is as broad, if not broader, than the dose spacing generally used in animal testing and thus removes the residual concern of the steepness of the dose-response curve and the severe effects noted.

Additionally, this adjusted point of departure (0.04 mg/kg/day) would address the concerns for the increased susceptibility seen at higher doses in the 2-generation reproduction study in rats (LOAEL = 0.4 mg/kg/day), prenatal developmental study in mice (LOAEL = 0.75 mg/kg/day), the prenatal developmental toxicity study in rabbits (LOAEL = 2 mg/kg/day), and the 1-generation rat reproduction study (LOAEL = 0.2 mg/kg/day).

With respect to acute dietary exposure, the endpoint selected for risk assessment is based on mydriasis observed in dogs. The EPA determined that the additional 3x factor applied to chronic and other exposure scenarios is not applicable to acute exposure for the following reasons:

a. The concerns noted for steepness of the dose-response curve and the severity of effects were not seen in the studies where mydriasis occurred.
b. The reduced body weights noted in studies following repeated exposure to abamectin (avermectin) are not a single dose effect.
c. The increased susceptibility seen in the prenatal developmental toxicity studies, reproductive toxicity studies, and the developmental neurotoxicity studies were seen at a dose lower (LOAEL 0.2 mg/kg/day) than the dose (LOAEL 1.0 mg/kg/day) that caused mydriasis.

Therefore, EPA has determined that it would be appropriate if the FQPA SF were reduced to 1X for the acute dietary assessment.

ii. The toxicity database for abamectin (avermectin) is complete, except for immunotoxicity testing. Recent changes to 40 CFR part 158 imposed new data requirements for immunotoxicity testing (OPPTS Guideline 870.7800) for pesticide

registration. However, the toxicity database for abamectin (avermectin) provides no indication of immunotoxicity and abamectin (avermectin) does not belong to a class of chemicals that would be expected to be immunotoxic. EPA does not believe that conducting an immunotoxicity study will result in a NOAEL less than the NOAELs of 0.5 mg/kg/day and 0.12 mg/kg/day already set for abamectin (avermectin) acute and repeated exposures, respectively, and an additional uncertainty factor is not needed to account for potential immunotoxicity.

iii. Signs of neurotoxicity ranging from decrease 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 were reported in various studies with different durations of abamectin (avermectin) exposure in rats, mice, and dogs. However, the results of two submitted rat developmental neurotoxicity studies did not show any evidence of neurotoxicity.

iv. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary exposure assessments were refined and utilized tolerance level or anticipated residues, default or empirical processing factors, and PCT estimates. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to abamectin (avermectin) in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by abamectin (avermectin).

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 (avermectin) will occupy 30% of the aPAD for infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to abamectin (avermectin) from food and water will utilize 50 % 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 (avermectin) is not expected.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Abamectin (avermectin) is currently registered for uses that could result in short- and intermediate-term residential exposures, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to abamectin (avermectin).

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs of 1200 for the general population and 500 for children 1-2 years old. Because EPA's level of concern for abamectin (avermectin) is a MOE of 300 or below, these MOEs are not of concern.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available in Pesticide Analytical Manual II (PAM II) for citrus and processed fractions (Method I), ginned cottonseed (Method IA), and bovine tissues and milk (Method II). Additionally, Method M-073 and M-936-95-2 have been validated by the Agency and submitted for inclusion in PAM II as enforcement methods. These five methods are adequate for enforcement of the tolerances on plants and livestock.

Method M-073 and M-936-95-2 may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

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

There are currently no Codex MRLs for abamectin (avermectin) on commodities associated with this petition.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA revised the proposed tolerance for chive, dried leaves from 0.07 ppm to 0.02 ppm. EPA revised the tolerance level based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data.* Additionally, the Agency has revised the tolerance expression to clarify:

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

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of abamectin (avermectin), 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 onion, bulb, subgroup 3-07A at 0.01 ppm; chive, fresh leaves at 0.01 ppm; chive, dried leaves at 0.02 ppm; and bean, dry, seed at 0.01 ppm. This regulation additionally removes the time-limited tolerances on bean, lima, seed at 0.005 ppm; and onion, bulb at 0.005 ppm, as they will be superseded by permanent tolerances.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under

Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National

Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: September 30, 2011.

Daniel J. Rosenblatt,

Acting 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. Section 180.449 is amended in paragraph (a) by revising the introductory text and alphabetically adding the following commodities to the table and by revising paragraph (b) to read as follows:

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

(a) *General*. Tolerances are established for residues of abamectin (avermectin), including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only 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 the following commodities:

Commodity	Parts per million
* * *	* *
Bean, dry, seed	0.01
* * *	* *
Chive, dried leaves	0.02
Chive, fresh leaves	0.01
* * *	* *
Onion, bulb, subgroup 3-07A	0.01
* * *	* *

(b) *Section 18 emergency exemptions*. [Reserved]

* * * * *

[FR Doc. 2011-28666 Filed 11/08/2011 at 8:45 am; Publication Date: 11/09/2011]