ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0418; FRL–9379–1]

Abamectin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation raises tolerances for residues of abamectin (also known as 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 delta-8,9-isomer) in or on cotton and strawberries. Syngenta Crop Protection Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 27, 2013. Objections and requests for hearings must be received on or before May 28, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0418, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Jessica Rogala, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (703) 347–0263; email address: *rogala.jessica@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.* To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/oppts* and select ''Test Methods and Guidelines.''

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–2012–0418 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 May 28, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0418, 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 Confidential Business Information (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.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 22, 2012 (77 FR 50661) (FRL–9358–9), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8009) by Syngenta Crop Protection LLC, P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.449 be amended by increasing the established tolerances for residues of the insecticide abamectin (also known as 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) (referred to as ''abamectin'' in this document) in or on cotton, undelinted seed from 0.005 parts per million (ppm) to 0.015 ppm; cotton, gin by-products from 0.15 ppm to 1.0 ppm and strawberry from 0.02 ppm to 0.06 ppm.

That document referenced a summary of the petition prepared by Syngenta Crop Protection LLC., 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 is establishing tolerance for cotton, undelinted seed and strawberry at levels that vary from levels requested. The reasons for these changes are explained in Unit IV.D.

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 has high to moderate acute toxicity by the oral route (depending on the vehicle), 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 is the nervous system, and the reduced body weight effect is one of the most frequent findings. Neurotoxicity and developmental effects were detected in multiple studies and species of test animals. The dose/response curve is very steep in several studies, with severe effects (including death and morbid sacrifice) seen at dose levels as low as 0.4 milligrams/kilogram/day (mg/kg/day) and 0.1 mg/kg/day in rats and mice, respectively, following repeated/chronic exposures. Increased susceptibility (qualitative and/or quantitative) was seen in prenatal developmental toxicity studies in mice and rabbits, and in developmental neurotoxicity studies in rats. Review of acceptable oncogenicity and mutagenicity studies provides 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 document, Abamectin: Human Health Risk Assessment at 16, section 4.0 in docket ID number EPA–HQ–OPP–2012–0418.

B. Toxicological Points of Departure/Levels of Concern

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

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 (General population including infants and children).	NOAEL = 0.5 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = .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	cPAD = .0004 mg/kg/day.	Combined data from three reproduction studies and two developmental neurotoxicity studies (please see the discussion on Chronic Dietary Endpoint) LOAEL = 0.2 mg/kg/day based on decreased pup body weight in pups at 0.2 mg/kg/day.
Incidental oral short-term and Intermediate term (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 from three reproduction studies and two developmental neurotoxicity studies (please see the discussion on Chronic Dietary Endpoint) LOAEL = 0.2 mg/kg/day based on decreased pup body weight.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ABAMECTIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Dermal All Durations	Dermal study NOAEL = 0.12 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 3x	LOC for MOE = 300	Combined data from three reproduction studies and two developmental neurotoxicity studies (please see the discussion on Chronic Dietary Endpoint) LOAEL = 0.2 mg/kg/day based on decreased pup body weight.
Inhalation short-term All durations	Inhalation study NOAEL = 0.12 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 3x	LOC for MOE = 300	Combined data from three reproduction studies and two developmental neurotoxicity studies (please see the discussion on Chronic Dietary Endpoint) LOAEL = 0.2 mg/kg/day based on decreased pup body weight.
Cancer (Oral, dermal, inhalation).	Classification: Not likely to be carcinogenic to humans based on the absence of significant increase in tumor incidence 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_{DB} = to account for the absence of data or other data deficiency. 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 2003–2008 food consumption information from the U.S. Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, a refined acute dietary (food and drinking water) exposure assessment was conducted. Tolerance level residues were used for bulb onions, chives, dry beans, and okra. Acute anticipated residues for the remaining commodities were derived from field trial data. Empirical and default processing factors were used. EPA also relied on available percent crop treated (PCT) information for registered uses of abamectin including strawberry and cotton. EPA relied on available data in estimating PCT) for existing uses of abamectin. Surface drinking water concentrations were estimated using the Tier II PRZM/EXAMS (Pesticide Root Zone Model/Exposure Analysis Modeling System) computer model and a national default percent cropped area (PCA) value of 87%. The model predicts that the maximum concentration of total residues of abamectin in surface water (the 1-in-10-year peak exposure) is not likely to exceed 2.3 ppb from the use of aerial/ground applications to dry beans in Michigan.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003–2008 food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA a refined chronic dietary exposure assessment was conducted. Tolerance level residues were used for bulb onions, chives, dry beans, and and okra. Average residues from field trials were used for the remaining crops. Empirical and default processing factors were also used. EPA used available PCT information registered use of abamectin including strawberry and cotton. Drinking water was represented by a single point estimate of average abamectin residues (the 1-in-ten-year annual mean). The estimated surface water concentration of 1.3 parts per billion (ppb) was based on the application to dry beans in Michigan.

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 quantitative 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 Agency estimated the PCT for existing uses as follows: The following maximum PCT estimates were used in the acute dietary risk assessment for the following crops that are currently registered for abamectin: 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%.

The following average PCT estimates were used in the chronic dietary risk assessment for the following crops that are currently registered for abamectin: 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%.

An emulsifiable concentrate (EC) formulation is currently registered for abamectin for use on cotton and strawberry. The petitioner has requested that the existing tolerance levels be increased to support the registration of cotton and strawberry for a suspension concentrate (SC) formulation. The residue field trials submitted indicate that the SC formulation result in higher pesticide residues than that of the EC formulation. However, the Agency does not expect that the registration of a different formulation will impact the PCT estimates.

In most cases, EPA uses available data from USDA 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 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://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 were used to estimate the drinking water concentrations (EDWCs) of abamectin. For acute exposures, the EDWCs are estimated to be 2.3 parts per billion (ppb) for surface water and 1.6×10^{-3} ppb for ground water. The EDWCs of abamectin for chronic exposures are estimated to be 1.3 ppb for surface water and 1.6×10^{-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 is currently registered for the following uses that could result in residential exposures: Granular baits used to treat lawns and indoor bait products. EPA assessed residential exposure using the following assumptions: Adults were assessed for short-term residential handler exposure. Residential post-application exposure to adults and children is unlikely for all registered uses of abamectin. 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.''

OPP's *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999) describes the weight of the evidence approach for determining whether or not a group of pesticides share a common mechanism of toxicity. This guidance defines mechanism of toxicity as the major steps leading to a toxic effect following interaction of a pesticide with biological targets. All steps leading to an effect do not need to be specifically understood. Rather, it is the identification of the crucial events following chemical interaction that are required in order to describe a mechanism of toxicity. For example, a mechanism of toxicity may be described by knowing the following: A chemical binds to a given biological target *in vitro,* and causes the receptor-related molecular response; *in vivo* it also leads

to the molecular response and causes a number of intervening biological and morphological steps that result in an adverse effect. In this context a common mechanism of toxicity pertains to two or more pesticide chemicals or other substances that cause a common toxic effect to human health by the same, or essentially the same, sequence of major biochemical events. Hence, the underlying basis of the toxicity is the same, or essentially the same, for each chemical. In the case of the macrocyclic lactone pesticides (e.g., abamectin, emamectin, and avermectin), there is a wealth of data on the insecticidal mechanism of action for avermectin: Its insecticidal actions are mediated by interaction with the glutamate-gated chloride channels and $GABA_A$ gated chloride channels. This is presumed to be the insecticidal mechanism of action of emamectin and abamectin as well. Insecticidal mechanism of action does not indicate a common mechanism of toxicity for human health. Further, mammals lack glutamate-gated chloride channels; the toxic actions of avermectin appear to be mediated via interaction with $GABA_A$ and possibly glycine gated chloride channels. There is evidence that avermectin B_{1a} binds to $GABA_A$ receptors and activates Cl^- flux into neurons (Abalis et al., 1986; Huang and Casida, 1997). However, there is a paucity of data regarding the resultant alterations in cellular excitability of mammalian neurons and neural networks (i.e., changes in cellular excitability and altered network function as documented with pyrethroids), as well as *in vivo* measurements of altered excitability associated with adverse outcomes. Thus, while the downstream steps leading to toxicity via disruption of $GABA_A$ receptor function for avermectin can be postulated, experimental data supporting these actions are lacking. In addition, specific data demonstrating $GABA_A$ receptor interaction in mammalian preparations are lacking for abamectin and emamectin. Moreover, the specificity of such interaction on the adverse outcome would need to be shown experimentally. $GABA_A$ receptors have multiple binding sites which have been proposed to relate to adverse outcomes. For example, Dawson et al (2000) showed for a group of avermectin-like compounds that rank order for anticonvulsant activity did not parallel the rank order for affinity at the 3H ivermectin site. The authors hypothesized that these findings may be related to differential affinity or efficacy at subtypes of the $GABA_A$ receptor. Other reports have indicated species differences in abamectin effects on $GABA_A$ receptor function in the mouse as compared to the rat (Soderlund et al., 1987).

In conclusion, although $GABA_A$ receptor mediated neurotoxicity may be a common mechanism endpoint for the macrocyclic lactone pesticides, data demonstrating the interactions of emamectin and abamectin with mammalian $GABA_A$ receptors are not available, and data in mammalian preparations linking alterations in $GABA_A$ receptor function to disruptions in neuronal excitability *in vitro* and *in vivo,* and ultimately adverse outcome, are also currently lacking for this class of compounds. In the absence of such data, the key biological steps leading to the adverse outcome (i.e., the mammalian mechanism of action) cannot be established and by extension a common mechanism of toxicity cannot be established.

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

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* The abamectin 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 the 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 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. The toxicity database for abamectin 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 provides no indication of immunotoxicity and abamectin does not belong to a class of chemicals that would be expected to be immunotoxic. Therefore, 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 acute and repeated exposures, respectively, and an additional uncertainty factor is not needed to account for lack of an immunotoxicity study.

ii. 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 exposure in rats, mice, and dogs. However, the results of two submitted rat developmental neurotoxicity studies did not show any evidence of neurotoxicity.

iii. For all risk assessments involving repeated exposures to abamectin, 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. 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 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.

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 in drinking water. These assessments will not underestimate the exposure and risks posed by abamectin. Residential post-application exposure to adults and children is unlikely for all registered uses of 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 percent adjusted dose (PAD) and chronic percent adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term, 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 24% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to abamectin from food and water will utilize 53% of the cPAD for children 1–2 years old the population group receiving the greatest exposure.

3. *Short-term and intermediate-term risk.* Short-term 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 is currently registered for uses that could result in short- and/or intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and/or intermediate-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 an aggregate MOE of 1800 for the general population Residential post-application exposure to adults and children is unlikely for all registered uses of abamectin. Because EPA's level of concern for abamectin is an MOE of 300 or below, this MOE is 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 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 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; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for abamectin.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA revised the proposed tolerance for cotton, undelinted seed from 0.015 ppm to 0.02 ppm and strawberry from 0.06 to 0.05 ppm. The established tolerances are based on residue data using the EC

formulation. Residues from crop field trials using the suspension concentrate (SC) formulation of abamectin plus adjuvant are higher than the established tolerances on cotton and strawberry, which are based on the EC formulation; therefore, higher tolerances are needed for use of the SC formulation on cotton and strawberry. 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 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 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 undelinted cotton seed at 0.02 ppm, cotton gin byproducts at 1.0 ppm, and strawberry at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 18, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

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

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

■ 2. In 180.449 is amended in paragraph (a) by:

■ i. Revising the introductory text.

■ ii. Revising in the table, the tolerance levels for Cotton, gin byproducts; Cotton, undelinted seed; and Strawberry to read as follows.

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

(a) *General.* Tolerances are established for residues of abamectin, 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 B1 a mixture of avermectins containing greater than or equal to 80% avermectin B1 a (5-*O*-demethyl avermectin A1) and less than or equal to 20% avermectin B1b (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A1) and its delta-8,9-isomer in or on the following commodities:

Commodity	Parts per million
* * * * * * *	
Cotton, gin byproducts	1.0
Cotton, undelinted seed	0.02

Commodity						Parts per million
*	*	*	*	*	*	*
Strawberry						0.05
*	*	*	*	*	*	*

[FR Doc. 2013–06916 Filed 3–26–13; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2012–0842; FRL–9382–2]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances; Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical amendment.

SUMMARY: EPA issued direct final significant new use rules (SNURS) in the **Federal Register** of December 20, 2012 for 9 chemical substances which were the subject of premanufacture notices (PMNs). For the chemical substance identified generically as aromatic sulfonic acid amino azo dye salts (PMN P–12–276) a typographical error has been identified. This document is being issued to correct the typographical error.

DATES: This final rule is effective March 27, 2013.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2012–0842, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. 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 OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

The Agency included in the final rule a list of those who may be potentially affected by this action.

II. What does this technical amendment do?

When promulgating the significant new uses for aromatic sulfonic acid amino azo dye salts, EPA inadvertently listed the respirator as M100 in the workplace protective equipment requirements for § 721.63. EPA did not intend to include this requirement when promulgating the significant new uses for aromatic sulfonic acid amino azo dye salts; the Agency intended the respirator to be designated as N100. This technical amendment corrects that workplace protective equipment requirement for § 721.63.

The preamble for FR Doc. 2012–30695 published in the **Federal Register** issue of December 20, 2012 (77 FR 75390) (FRL–9372–8) is corrected as follows:

1. On page 75394, first column, line 16, correct M100 to read N100.

III. Why is this technical amendment issued as a final rule?

Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)) provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making this technical amendment final without prior proposal and opportunity for comment, because notice and comment are unnecessary. The respirator designation of M100 that is being removed was never intended to be included in the SNUR; M100 is a designation for a 3M Corporation series of respiratory face shield, not a respirator; the Agency intended it to be a National Institute for Occupational Safety and Health (NIOSH)-certified N100 respirator. The PMN submitter who brought the error to EPA's attention is familiar with the issue, and EPA is not aware of and does not expect there to be persons who would be adversely affected by the change as there are no companies making plans based on the erroneous notice and no harm resulting from replacing the erroneous requirement for a M100 respirator with that of a N100 respirator. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(3)(B).

IV. Do any of the statutory and executive order reviews apply to this action?

This technical amendment changes an erroneous respirator designation that was placed in § 721.10633(a)(2)(i) when the final rule published in the **Federal Register** of December 20, 2012, promulgating significant new uses of aromatic sulfonic acid amino azo dye salts. The December 20, 2012 final rule addresses these requirements for that action (see Unit IX. of the preamble to that action). This technical amendment does not otherwise amend or impose any other requirements.

As such, this technical amendment is not a ''significant regulatory action'' subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), nor does this technical amendment contain any information collections subject to OMB approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Because the Agency has made a ''good cause'' finding that this technical amendment is not subject to notice and comment requirements under the APA or any other statute (see Unit III. of this document), it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), or to sections 202