■ 25. Revise sections 4.1 and 5.2.2.2 to Appendix A to Subpart UUUUU of Part 63 to read as follows:

Appendix A to Subpart UUUUU—Hg Monitoring Provisions

* * * * *

4.1 *Certification Requirements.* All Hg CEMS and sorbent trap monitoring systems and the additional monitoring systems used to continuously measure Hg emissions in units of the applicable emissions standard in accordance with this appendix must be certified in a timely manner, such that the initial compliance demonstration is completed no later than the applicable date in § 63.9984(f).

* * * * *

5.2.2.2 The same RATA performance criteria specified in Table A–2 for Hg CEMS also apply to the annual RATAs of the sorbent trap monitoring system.

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■ 26. Revise section 3.1.2.1.3 and the heading to section 5.3.4 to Appendix B to Subpart UUUUU of Part 63 to read as follows:

Appendix B to Subpart UUUUU—HCl and HF Monitoring Provisions

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3.1.2.1.3 For the ASTM D6348–03 test data to be acceptable for a target analyte, %R must be 70% ≤ R ≤ 130%; and

* * * * *

5.3.3 *Conditional Data Validation*

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[FR Doc. 2013–07859 Filed 4–23–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0282; FRL–9384–2]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of azoxystrobin in or on multiple commodities discussed later in this document. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 24, 2013. Objections and requests for hearings must be received on or before June 24, 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 these actions, identified by docket identification (ID) number EPA–HQ–OPP–2012–0282, 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: Erin Malone, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0253; email address: *Malone.Erin@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 eCFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0282 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 June 24, 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–2012–0282, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.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 April 4, 2012 (77 FR 20336) (FRL–9340–4), 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 1E7945) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.507 be amended by establishing an import tolerance for residues of the fungicide azoxystrobin, [methyl(E)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate], and the *Z*-isomer of azoxystrobin, [methyl(*Z*)-2-(2-(6-(2-

cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] in or on ginseng extract (red ginseng extract and ginseng extract) at 0.5 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket EPA–HQ–OPP–2012–0041, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Additionally, in the **Federal Register** of May 23, 2012 (77 FR 30484) (FRL–9347–8), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 2F7976 and PP 2F7984) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419–8300. The petitions requested that 40 CFR 180.507 be amended by:

- Establishing tolerances for residues of the fungicide azoxystrobin, [methyl(E)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and the *Z*-isomer of azoxystrobin, [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate], in or on oats, forage at 4 parts per million (ppm); oats, hay at 7 ppm; oats, straw at 3 ppm; oats, grain at 1 ppm; rye, forage at 4 ppm; rye, straw at 0.8 ppm; rye, grain at 0.07 ppm; poultry, meat at 0.01 ppm; poultry, liver at 0.2 ppm; poultry, fat at 0.01 ppm; egg at 0.1 ppm; cattle, liver at 0.5 ppm; cattle, kidney at 0.1 ppm; hog, liver at 0.2 ppm; hog, kidney at 0.03 ppm (PP 2F7976);

- Amending established tolerances for barley, hay from 15 ppm to 7 ppm; barley, straw from 7 ppm to 8 ppm; barley, grain from 3 ppm to 2 ppm; wheat, forage from 25 ppm to 10 ppm; wheat, straw from 4 ppm to 6 ppm; wheat, hay from 15 ppm to 20 ppm; grain aspirated fractions from 420 ppm to 460 ppm; cattle, fat from 0.03 ppm to 0.3 ppm; hog, fat from 0.01 ppm to 0.1 ppm; hog, meat from 0.01 ppm to 0.02 ppm; (PP 2F7984).

The notices referenced summaries of the petitions prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the dockets EPA–HQ–OPP–2012–0282 and EPA–HQ–OPP–2012–0283, *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 tolerances that vary from what the petitioner requested. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.* * *''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for azoxystrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with azoxystrobin 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.

The toxicological profile for azoxystrobin has not changed since the final rule published in the **Federal Register** of July 13, 2012 (77 FR 41285) (FRL–9352–2). See that rule for a summary of the toxicological profile and references to supporting Agency documents that discuss specific information on the toxicity studies received and the nature of the adverse effects caused by azoxystrobin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL).

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 azoxystrobin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of July 13, 2012 (77 FR 41286) (FRL–9352–2).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to azoxystrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing azoxystrobin tolerances in 40 CFR 180.507. EPA assessed dietary exposures from azoxystrobin 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 azoxystrobin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in

America (NHANES/WWEIA) conducted from 2003 to 2008. As to residue levels in food, the acute dietary exposure assessment of azoxystrobin is partially refined by using highest residue values for citrus fruits and assuming tolerance-level residues for all other existing and proposed commodities. One hundred percent of the crops were assumed treated with azoxystrobin and DEEM (Dietary Exposure Evaluation Model) version 7.81 default processing factors were used except where tolerances were established for processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA's (NHANES/WWEIA) conducted from 2003 to 2008, as well. As to residue levels in food, a slightly refined chronic dietary analysis for azoxystrobin was conducted using tolerance-level residues and average percent crop treated estimates when available. DEEM version 7.81 default processing factors were assumed except for where tolerances were established for processed commodities or when processing studies show no concentration. An updated screening level usage analysis (SLUA) of azoxystrobin from 2011 was used for percent crop treated.

iii. *Cancer.* The rat and the mouse carcinogenicity studies on azoxystrobin do not show an increase in tumor incidence. Azoxystrobin is classified as ''not likely to be carcinogenic to humans.'' Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated or actual residues and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data 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: Almonds, 25%; apricots, 10%; artichokes, 25%; asparagus, 2.5%; green beans, 10%; blackberries, 5%; blueberries, 10%; broccoli, 5%; cabbage, 10%; cantaloupes, 10%; carrots, 10%; cauliflower, 2.5%; celery, 10%; cherries, 5%; corn, 2.5%; cotton, 5%; cucumbers, 20%; dry beans/peas, 1%; garlic, 60%; grapefruit, 20%; grapes, 5%; hazelnuts (filberts), 5%; lettuce, 2.5%; onions, 10%; oranges, 5%; peaches, 5%; peanuts, 15%; green peas, 2.5%; pecans, 2.5%; peppers, 15%; pistachios, 15%; potatoes, 35%; prunes, 2.5%; pumpkins, 20%; raspberries, 5%; rice, 35%; soybeans, 2.5%; spinach, 10%; squash, 15%; strawberries, 30%; sugar beets, 5%; sweet corn, 10%; tangerines, 15%; tomatoes, 15%; walnuts, 1%; watermelon, 20%; and wheat, 2.5%.

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 1%. 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 azoxystrobin 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 azoxystrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of azoxystrobin. 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 First Index Reservoir Screening Tool (FIRST), the highest estimated drinking water concentrations (EDWCs) of azoxystrobin for acute exposures are estimated to be 173 parts per billion (ppb) for surface water and 33 ppb for chronic exposures for non-cancer assessments. Based on the Screening Concentration in Groundwater, version 2.3, August 8, 2003 (SCI-GROW), the EDWC for ground water is 3.1 ppb for all exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 173 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 33 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). Azoxystrobin is currently registered for the following uses that could result in residential exposures: Outdoor residential (lawns, ornamentals, flower gardens, vegetables, fruit and nut trees, berries and vines) and recreational (golf courses, parks and athletic fields) sites. Additionally, azoxystrobin is registered for uses on indoor carpets/other surfaces, and in treated paints (preservative incorporation). EPA assessed residential exposure using the following assumptions:

- Residential uses will result in short-term (1 to 30 days) handler exposure; residential handlers are assumed to be wearing short-sleeved shirts, short pants, shoes, and socks during the application; and because there was no dermal endpoint chosen for azoxystrobin, residential handler risk from exposure was assessed for the inhalation route only.
- The Agency assumed that post-application exposure in residential settings is expected to be short-term in duration only. Residential post-application inhalation exposure in outdoor settings is considered negligible; however, residential post-application inhalation exposure in indoor settings has been assessed for adults and children.

Further information regarding EPA's 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 azoxystrobin to share a common mechanism of toxicity with any other substances, and azoxystrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that azoxystrobin 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 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 prenatal and postnatal toxicity database for azoxystrobin is complete and includes prenatal developmental toxicity studies in rats and rabbits and a 2-generation study in rats. In these studies, offspring toxicity was observed at equivalent or higher doses than those resulting in parental toxicity; thus, there is no evidence of increased susceptibility and there are no residual uncertainties with regards to prenatal and/or postnatal toxicity.

3. *Conclusion.* EPA has retained the FQPA SF, reduced to 3X, in assessing acute dietary risk. An additional safety factor is needed for acute risk assessment to account for the use of a LOAEL from the acute neurotoxicity study in rats in deriving the acute reference dose used for assessing acute dietary exposure for all populations including infants and children. To account for the use of a LOAEL from the acute neurotoxicity study in rats, the Agency believes that a 3X FQPA SF (as opposed to a 10X) will be adequate to extrapolate a NOAEL in assessing acute risk based on the following considerations:

- The effect seen (transient diarrhea seen in the rat) is of a nature that is relatively insignificant;
- The diarrhea was only seen in studies involving gavage dosing in the rat but not in repeat dosing through dietary administration in rats and mice, and not through gavage dosing in rabbits; and
- The very high dose level needed to reach the acute oral lethal dose $(LD)_{50}$ (>5,000 milligrams/kilogram (mg/kg)), and the overall low toxicity of azoxystrobin.

However, EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X for short-term, intermediate-term, and chronic risk assessment. This determination is based on the following considerations.

i. The toxicity database for azoxystrobin is complete except for immunotoxicity. Changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. There are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by azoxystrobin and azoxystrobin does not belong to a class of chemicals that would be expected to be immunotoxic. Based on the above considerations, EPA does not believe that conducting the immunotoxicity study will result in a dose less than the point of departure already used in this risk assessment and an additional database uncertainty factor for potential immunotoxicity does not need to be applied.

ii. Clinical signs, including transient diarrhea and decreased body weight, body weight gain, and food utilization, were noted in the acute and subchronic neurotoxicity studies, but were not considered indicative of neurotoxicity. There is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that azoxystrobin results in increased susceptibility to *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties in the azoxystrobin exposure database. While some refinements were incorporated into the dietary exposure calculations, EPA is confident that the aggregate risk from exposure to azoxystrobin in food, drinking water, and residential pathways will not be underestimated. The acute dietary (food) exposure assessment utilized conservative upper-bound inputs including 100% of the proposed and registered crops treated, and tolerance-level residues for all existing and proposed commodities, except citrus fruits where the highest field trial residue was used as a refinement. The chronic dietary exposure assessment was partially refined, and used tolerance-level residues for all commodities and PCT estimates when available (SLUA, 07/13/11). Although the acute and chronic assessments included minor refinements, the use of

field trial and PCT estimates ensures that actual exposures/risks from residues in food will not be underestimated. The drinking water assessment utilized water concentration values generated by models and associated modeling parameters which are designed to produce conservative, health protective, high-end estimates of water concentrations which are not likely to be exceeded. The dietary (food and drinking water) exposure assessment does not underestimate the potential exposure for infants, children, or women of child-bearing age.

In addition, the residential exposure assessment is based on the updated 2012 Residential SOPs employing surrogate study data, including conservative exposure assumptions based on Day 0 dermal/oral contact to turf and surfaces treated at the maximum application rate. These data are reliable and are not expected to underestimate risks to adults or children. The Residential SOPs are based upon reasonable ''worst-case'' assumptions and are not expected to underestimate risk.

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 aPAD and 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 aggregate risk would be equivalent to the acute dietary exposure from food and water to azoxystrobin will occupy 41% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of azoxystrobin is not expected. Therefore, the chronic aggregate risk would be equivalent to the chronic dietary exposure estimate and was 17% of the cPAD for the most highly exposed subgroup, children 1–2 years old.

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

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 920 for general U.S. population and 190 for children 1 to 2 years old. Because EPA's level of concern for azoxystrobin is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Azoxystrobin is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, EPA relies on chronic dietary exposure to evaluate intermediate-term aggregate risk.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available to enforce the tolerance expression and have been submitted to FDA for inclusion in the Pesticide Analytical Manual (PAM) Volume II: A gas chromatography method with nitrogen-phosphorus detection (GC/NPD), RAM 243/04, for the enforcement of tolerances for residues of azoxystrobin and its Z-isomer in crop commodities; and a GC/NPD method, RAM 255/01, for the enforcement of tolerances of azoxystrobin in livestock commodities.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

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

The Codex has not established MRLs for azoxystrobin on oat, forage; oat, hay; rye, forage; barley, hay; wheat, forage; wheat, hay; and grain aspirated fractions.

The Codex has established MRLs for azoxystrobin in or on ginseng, dried including red ginseng at 0.5 ppm; rye, grain at 0.2 ppm and wheat, grain at 0.2 ppm. These MRLs are the same as the tolerances established for azoxystrobin in the United States.

The Codex has established MRLs for azoxystrobin in or on oats, grain at 0.5 ppm and barley, grain at 0.5 ppm. These MRLs are different than the tolerances established for azoxystrobin in the United States. The U.S. tolerance on oat grain (1.5 ppm) and barley grain (3 ppm) could not be harmonized since the Codex MRLs are lower. Setting the U.S. tolerance to be consistent with the Codex MRLs might lead to residues in excess of the tolerance, despite legal use of the pesticide in accordance with the registered label.

C. Revisions to Petitioned-For Tolerances

The tolerance levels requested by the petitioners are based on residue data submitted using lower application rates than are found on the registered label; therefore, EPA used the proportionality principle (JMPR Report 2011) to estimate residue values that reflect the higher application rates on the registered label. In doing this exercise, EPA determined that an adjustment to the wheat, grain tolerance was required to reflect the application rates for the pesticide.

The proposed tolerance on ginseng extract (red ginseng extract and ginseng

extract) is not needed because the tolerance on ginseng will cover the expected residues in these processed commodities.

The proposed amended tolerance for grain aspirated fractions is not needed due to the current tolerance being sufficient. EPA is not establishing the tolerances as proposed for livestock commodities as there was no increased dietary burden on livestock with the new uses, the existing tolerances were sufficient.

The tolerance expression in 40 CFR 180.507(a)(2) is incorrect and was revised.

V. Conclusion

Therefore, tolerances are established for residues of azoxystrobin, [methyl(E)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate and the *Z*-isomer of azoxystrobin, [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate], in or on oat, forage at 5.0 ppm; oat, hay at 10.0 ppm; oat, straw at 3.0 ppm; oat, grain at 1.5 ppm; rye, forage at 7.0 ppm; rye, straw at 1.5 ppm; rye, grain at 0.2 ppm; barley, hay at 10.0 ppm; barley, straw 15.0 ppm; wheat, forage from at 15.0 ppm; wheat, straw at 10.0 ppm; wheat, hay at 30.0 ppm; and wheat, grain at 0.2 ppm. In conjunction with establishment of the wheat grain tolerance at 0.2 ppm, the existing tolerance on wheat bran needs to be deleted from 40 CFR 180.507(a)(1).

Also, EPA is establishing a tolerance for residues of azoxystrobin [methyl(E)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and the *Z*-isomer of azoxystrobin, [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate], in or on ginseng at 0.5 ppm. Although, as of the date of publication of this rule, there are no U.S. registrations for use of azoxystrobin on ginseng, this tolerance will allow for imports of treated ginseng meeting this tolerance level.

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: April 12, 2013.

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. In § 180.507:

■ a. Revise the entries for ''Barley, hay'', ''Barley, straw'', ''Wheat, grain'', ''Wheat, hay'', ands ''Wheat, straw'' in the table in paragraph (a)(1);

■ b. Add alphabetically the entries for ''Ginseng'', ''Oats, forage'', ''Oats, grain'', ''Oats, hay'', ''Oats, straw'', ''Rye, forage'', ''Rye, grain'', ''Rye, straw'' to the table in paragraph (a)(1);

■ c. Remove the entry in the table in paragraph (a)(1) for ''Wheat, bran'';

■ d. Add footnote 1 to the table in paragraph (a)(1); and

■ e. Revise the introductory text of paragraph (a)(2)

The revisions and additions read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Barley, hay	10.0
Barley, straw	15.0
* * * * *	
Ginseng [1]	0.5
* * * * *	
Oats, forage	5.0
Oats, grain	1.5
Oats, hay	10.0
Oats, straw	3.0
* * * * *	
Rye, forage	7.0
Rye, grain	0.2
Rye, straw	1.5

Commodity	Parts per million
* * * * *	
Wheat, grain	0.2
Wheat, hay	30.0
Wheat, straw	10.0

[1] There are no United States registrations for use of azoxystrobin on ginseng.

(2) Tolerances are established for residues of the fungicide, azoxystrobin, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the table is to be determined by measuring only azoxystrobin, [methyl(*E*)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] in or on the commodity.

* * * * *

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