costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 11, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action finalizing the limited approval of the Pennsylvania Regional Haze SIP may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2) of the CAA.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: June 15, 2012.

W.C. Early,

Acting Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart NN— Pennsylvania

■ 2. In § 52.2520, the table in paragraph (e) is amended by adding an entry for Regional Haze Plan at the end of the table to read as follows:

§ 52.2020 Identification of plan.

* * * * *

(e)* * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
Regional Haze Plan	Statewide	12/20/10	7/13/12 [*Insert page number where the document begins*].	§ 52.2042; Limited Approval.

[FR Doc. 2012–16428 Filed 7–12–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0398; FRL–9352–2]

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 which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) and Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 13, 2012. Objections and requests for hearings must be received on or before September 11, 2012, 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–2011–0398; FRL–9352–2, is available either electronically through *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, 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: Andrew Ertman, Registration Division, (7505P) Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; email address: *ertman.andrew@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2011–0398 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 September 11, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0398, 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), Mail Code: 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 Tolerances

In the **Federal Register** of July 20, 2011 (76 FR 43231) (FRL–8880–1), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7851) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition 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]pheny1]-3-methoxyacrylate) in or on onion, bulb subgroup 3–07A at 1.0 parts per million (ppm); onion, green subgroup 3–07B, at 7.5 ppm; caneberry subgroup 13–07A, at 5.0 ppm; bushberry subgroup 13–07B, at 3.0 ppm; small fruit vine climbing subgroup, except fuzzy kiwifruit, 13–07F, at 1.0 ppm; low growing berry subgroup 13–07G, except cranberry, at 10.0 ppm; vegetable, fruiting, subgroup 8–10A, at 0.2 ppm; vegetable, fruiting, subgroups 8–10B, at 2.0 ppm; fruit, citrus, group 10–10, at 10.0 ppm; rapeseed subgroup 20A, at 1.0 ppm; sunflower subgroup 20B, at 0.5 ppm; cottonseed subgroup 20C, at 0.6 ppm; wasabi, at 50.0 ppm; and dragon fruit, at 2.0 ppm;
- Changing the tolerance for vegetable, tuberous and corm, subgroup 1C from 0.03 ppm to 6.0 ppm; and
- Upon approval of the tolerances above, by removing the established tolerances for onion, bulb at 1.0 ppm; onion, green at 7.5 ppm; caneberry subgroup 13–A at 5.0 ppm; bushberry subgroup 13B at 3.0 ppm; Juneberry at 3.0 ppm; lingonberry at 3.0 ppm; salal at 3.0 ppm; grape at 1.0 ppm; strawberry at 10.0 ppm; tomato at 0.2 ppm; vegetable, fruiting, group 8 except tomato at 2.0 ppm; fruit, citrus, group 10 at 10.0 ppm; canola, seed at 1.0 ppm; cotton, undelinted seed at 0.6 ppm; crambe, seed at 0.5 ppm; flax, seed at 0.5 ppm; mustard, field, seed at 0.5 ppm; mustard, Indian, seed at 0.5 ppm; mustard, seed at 0.5 ppm; rapeseed, Indian at 0.5 ppm; rapeseed, seed at 0.5 ppm; safflower, seed at 0.5 ppm; sunflower, seed at 0.5 ppm; potato at 0.03 ppm.

In the **Federal Register** of November 9, 2011 (76 FR 69690) (FRL–9325–1), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7891) 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 a 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 sugarcane at 0.2 ppm.

The notices referenced summaries of the petitions prepared by Syngenta, the registrant, which are available in the docket, *http://www.regulations.gov.* There were no comments received in response to these notices of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established for various commodities. 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.

Azoxystrobin has low acute toxicity via the oral, dermal and inhalation routes of exposure. It is not an eye or skin irritant and is not a skin sensitizer. Dietary administration of azoxystrobin to rats resulted in decreased body weights, decreased food intake and utilization, increased diarrhea and other clinical toxicity observations (increased urinary incontinence, hunched postures and distended abdomens). In addition, liver effects characterized by increased liver weights, increases in alkaline phosphatase and gama glutamyltransferase, decreases in albumin, gross and histological lesions in the liver and bile ducts, were seen in rats. In dogs, effects on liver/biliary function were found after oral administration.

In the acute neurotoxicity study in rats, increased incidence of diarrhea was observed at all dose levels tested including the lowest-observed-adverse-effect-level (LOAEL). Decreased body weight/weight gain and food utilization was noted in the rat subchronic neurotoxicity study. There were no consistent indications of treatment-related neurotoxicity in either the acute or subchronic neurotoxicity studies.

In the rat developmental toxicity study, diarrhea, urinary incontinence and salivation were observed in maternal animals; in the rabbit developmental toxicity study, maternal animals exhibited decreased body weight gain. No adverse treatment-related developmental effects were seen in either study. In the rat reproduction study, offspring and parental effects (decreased body weights and increased adjusted liver weights) were observed at the same dose.

There was no evidence of carcinogenicity in rats and mice at acceptable dose levels. As a result, EPA has classified azoxystrobin as ''not likely to be carcinogenic to humans.'' Azoxystrobin induced a weak mutagenic response in the mouse lymphoma assay, but the activity expressed *in vitro* is not expected to be expressed in whole animals.

Specific information on the studies received and the nature of the adverse effects caused by azoxystrobin as well as the no-observed-adverse-effect-level (NOAEL) and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2011–0398 on pages 38–40 of the document titled ''Azoxystrobin: Human Health Risk Assessment for Proposed Uses on Dragon Fruit, Wasabi, and Tuberous and Corm Vegetables (Subgroup 1C), and from the Revisions to Various Crop Groups (Onion Subgroups 3–07 A, B; Fruiting Vegetable Subgroups 8–10 A, B; Small Fruit and Berry Subgroups 13–07 A, B, F, G, Oilseeds Subgroups A, B, C; and Citrus Fruit Group 10–10).''

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 shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR AZOXYSTROBIN 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 (All Populations)	LOAEL = 200 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 3x UF_L	Acute RfD = 0.67 mg/kg/day ..... aPAD = 0.67 mg/kg/day	Acute Neurotoxicity—Rat. LOAEL = 200 mg/kg/day based on diarrhea at 2-hours post dose at all dose levels up to and including to LOAEL.
Chronic dietary (All Populations) ...	NOAEL= 18 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.18 mg/kg/day ..... cPAD = 0.18 mg/kg/day	Combined Chronic Toxicity/Carcinogenicity Feeding Study—Rat. LOAEL = 82.4/117 mg/kg/day (M/F) based on reduced body weights in both sexes and bile duct lesions in males.
Incidental oral short-term (1 to 30 days).	NOAEL= 25 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Prenatal Developmental Oral Toxicity—Rat. LOAEL = 100 mg/kg/day based on increased maternal diarrhea, urinary incontinence, and salivation.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR AZOXYSTROBIN 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
Inhalation short-term (1 to 30 days).	Oral study NOAEL= 25 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Prenatal Developmental Oral Toxicity—Rat. LOAEL = 100 mg/kg/day based on increased maternal diarrhea, urinary incontinence, and salivation.

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. mg/kg/day = milligrams/kilogram/day.

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 U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, the acute dietary assessment used tolerance levels for all commodities, except citrus fruits where the highest residue from crop field trials was used, and 100 percent crop treated (PCT) for all commodities. Default processing factors were assumed except for 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 1994–1996 and 1998 CSFII. As to residue levels in food, the chronic dietary analysis for azoxystrobin was conducted using tolerance levels and average PCT estimates when available. Default processing factors were assumed except for where tolerances were established for processed commodities.

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

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data 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%; wheat, 2.5%.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (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), Screening Concentration in Ground Water (SCI-GROW), the Pesticide Root Zone Model (PRZM) and the Exposure Analysis Modeling System (EXAMS) models, the estimated drinking water concentrations (EDWCs) of azoxystrobin for acute exposures are estimated to be 173 parts per billion (ppb) and 33 ppb for chronic exposures. For ground water, the estimated drinking water concentration is 3.1 ppb.

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 of value 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, it is registered for use on indoor carpets/other surfaces by non-commercial applicators, and in treated paints (preservative incorporation). EPA assessed residential exposure using the new 2012 updated residential standard operating procedures (SOPs) that are now used in all human health assessments. For residential handler exposure, the Agency assumed that most residential use will result in short-term (1 to 30 days) dermal and inhalation exposures. The worst-case scenario used was painting with an airless sprayer. Residential handlers are assumed to be wearing short-sleeved shirts, short pants, shoes and socks during application of azoxystrobin. Because there was no dermal endpoint chosen for azoxystrobin, residential handler risk from exposure to azoxystrobin 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. No dermal endpoint was chosen for azoxystrobin; therefore, a dermal post-application risk assessment was not conducted. Residential post-application inhalation exposure in outdoor settings is considered negligible; however, residential post-application inhalation exposure has been assessed. The scenarios evaluated were short-term post-application inhalation (indoor), short-term incidental oral ingestion from treated indoor surfaces (hand-to-mouth vinyl/hard surfaces and carpet/textile surfaces), and short-term incidental oral ingestion from treated turf (hand-to-mouth, mouthing grass, and soil ingestion).

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.*

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 reproduction 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 regard to prenatal and/or postnatal toxicity.

3. *Conclusion.* 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 testing. 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 (e.g., the organotins,

heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on the above considerations in this unit, 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 (UF) for potential immunotoxicity does not need to be applied.

ii. Clinical signs noted in the acute and subchronic neurotoxicity studies were not considered treatment related because of a lack of dose-response, inconsistency of observations at different time points, variability of pretreatment values and/or small magnitude of response. 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. The acute dietary exposure assessment was performed based on tolerance-level residues for all crops except citrus, and the chronic dietary exposure assessment was performed based on tolerance level residues for all crops. The acute dietary assessment incorporated 100 PCT information, and the chronic dietary exposure assessment was somewhat refined using PCT information for selected crops. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to azoxystrobin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by azoxystrobin.

Despite these considerations supporting removal of the FQPA SF, 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 and that no additional safety factor is needed for short-term, intermediate-term, and chronic risk assessment 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.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to azoxystrobin will occupy 42% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to azoxystrobin from food and water will utilize 16% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of azoxystrobin is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

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 460 for adult males, 470 for females 13 to 49 years old and 200 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).

An intermediate-term adverse effect was identified; however, azoxystrobin is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for azoxystrobin.

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 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 following tolerances being established by this document are in harmony with the equivalent Codex MRLs are harmonized (Codex commodities in brackets): Caneberry subgroup 13–07A (berries and other small fruits, except cranberry, grapes and strawberry); berry, low growing, subgroup 13–07G, except cranberry (strawberries); sunflower subgroup 20B (sunflower seed); bushberry, subgroup 13–07B (berries and other small fruits, except cranberry, grapes and strawberry); cottonseed, subgroup 20C (cotton seed); fruit, citrus, group 10–10 (citrus fruits); fruit, small vine climbing, except fuzzy kiwifruit, 13–07F (grape); and pepper/eggplant subgroup 8–10B (fruiting vegetables other than cucurbits except mushrooms and sweet corn). The following tolerances could not be harmonized with Codex MRLs: Berry, low growing subgroup 13–07G, except cranberry (berries and other small fruits, except cranberry, grapes and strawberry); dragon fruit (mango); onion, bulb and green subgroups 3–07A & B (bulb vegetables); tomato subgroup 8–10A (fruiting vegetables other than cucurbits except mushrooms and sweet corn); vegetable, tuberous and corm subgroup 1C (root and tuber vegetables); and wasabi fresh and dry (herbs, fresh and dry). The disharmony is caused by various issues, including different Codex classification for crop grouping, different calculation procedures for establishing MRLs, different use patterns, and different data sets. There are no Codex MRLs) for residues of azoxystrobin and its Z-isomer for sugarcane.

C. Revisions to Petitioned-For Tolerances

Several of the tolerances have been revised from what was proposed in the initial petition. EPA is increasing the proposed crop group tolerances for bushberry, subgroup 13–07B; cottonseed subgroup 20C; citrus fruit, group 10–10; fruit, small vine climbing, except fuzzy kiwifruit subgroup 13–07F, and pepper/eggplant subgroup 8–10B to harmonize the numerical portion of the tolerance with the Codex MRL. Also, based on the Organization for Economic Cooperation and Development (OECD) calculation procedures for the current post-harvest potato use data, EPA increased the requested tolerance for vegetable, tuberous and corm, subgroup 1C from 6.0 ppm to 8.0 ppm. It should be noted that there is an existing tolerance on potato at 0.03 ppm that is based on foliar use. The substantial increase from 0.03 ppm to 8.0 ppm results from the post-harvest use, as opposed to the previous foliar-only use.

EPA is also revising some of the commodity definitions in the tolerance table to be consistent with EPA's preferred terms for food and feed.

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 onion, bulb, subgroup 3–07A at 1.0 ppm; onion, green, subgroup 3–07B at 7.5 ppm; tomato subgroup 8–10A at 0.2 ppm; pepper/eggplant subgroup 8–10B at 3.0 ppm; fruit, citrus, group 10–10 at 15.0 ppm; caneberry subgroup 13–07A at 5.0 ppm; bushberry subgroup 13–07B at 5.0 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2.0 ppm; berry, low growing, subgroup 13–07G, except cranberry at 10.0 ppm; rapeseed subgroup 20A at 1.0 ppm; sunflower subgroup 20B at 0.5 ppm; cottonseed subgroup 20C at 0.7 ppm; wasabi, fresh at 50 ppm; wasabi, dry at 260 ppm; dragon fruit at 2.0 ppm; vegetable, tuberous and corm, subgroup 1C at 8.0 ppm, and sugarcane, cane at 0.2 ppm.

And lastly, due to the tolerances established above by this document, the following existing tolerances are removed as unnecessary: Onion, bulb; onion, green; caneberry subgroup 13A; bushberry subgroup 13B; Juneberry; lingonberry; salal; grape; strawberry; tomato; vegetable, fruiting, group 8 except tomato; fruit, citrus, group 10; canola, seed; cotton, undelinted seed; crambe, seed; flax, seed; mustard, field, seed; mustard, Indian, seed; mustard, seed; rapeseed, Indian; rapeseed, seed; safflower, seed; sunflower, seed; potato; okra.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to petitions 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) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 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: July 3, 2012.

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 § 180.507 revise the table in paragraph (a)(1) to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Acerola	2.0
Almond, hulls	4.0
Animal feed, nongrass, group 18, forage	45
Animal feed, nongrass, group 18, hay	120
Artichoke, globe	4.0
Asparagus	0.04
Atemoya	2.0
Avocado	2.0
Banana	*
Barley, bran	6.0
Barley, forage	25
Barley, grain	3.0
Barley, hay	15.0
Barley, straw	7.0
Berry, low growing, subgroup 13–07G, except cranberry	10.0
Biriba	2.0
Brassica, head and stem, subgroup 5A	3.0
Brassica, leafy greens, subgroup 5B	25
Bushberry subgroup 13–07B	5.0
Caneberry subgroup 13–07A	5.0
Canistel	2.0
Cherimoya	2.0
Cilantro, leaves	30.0
Citrus, dried pulp	20.0
Citrus, oil	40.0
Corn, field, forage	12.0
Corn, field, grain	0.05
Corn, field, refined oil	0.3
Corn, field, stover	25.0
Corn, pop, grain	0.05
Corn, pop, stover	25.0
Corn, sweet, forage	12.0
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	25.0
Cotton, gin byproducts	45
Cottonseed subgroup 20C	0.7
Cranberry	0.50
Custard apple	2.0
Dragon fruit	2.0
Feijoa	2.0
Fruit, citrus, group 10–10	15.0
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	2.0
Fruit, stone, group 12	1.5
Grain, aspirated fractions	420
Grass, forage	15
Grass, hay	20
Guava	2.0
Herb Subgroup 19A, dried leaves	260
Herb Subgroup 19A, fresh leaves	50
Hop, dried cones	20.0
Ilama	2.0
Jaboticaba	2.0
Jackfruit	2.0
Longan	2.0
Loquat	2.0
Lychee	2.0
Mango	2.0
Nut, tree, group 14	0.02
Onion, bulb, subgroup 3–07A	1.0
Onion, green, subgroup 3–07B	7.5
Papaya	2.0
Passionfruit	2.0
Pawpaw	2.0
Pea and bean, dried shelled, except soybean, subgroup 6C	0.5
Pea and bean, succulent shelled, subgroup 6B	0.5
Peanut	0.2
Peanut, hay	15.0
Peanut, refined oil	0.6
Pepper/eggplant subgroup 8–10B	3.0
Peppermint, tops	30
Persimmon	2.0
Pistachio	0.50
Pulasan	2.0
Rambutan	2.0
Rapeseed subgroup 20A	1.0
Rice, grain	5.0
Rice, hulls	20
Rice, straw	12
Rice, wild, grain	5.0
Sapodilla	2.0
Sapote, black	2.0
Sapote, mamey	2.0
Sapote, white	2.0
Sorghum, grain, forage	25
Sorghum, grain, grain	11
Sorghum, grain, stover	40
Soursop	2.0
Soybean, hay	55.0
Soybean, hulls	1.0
Soybean, seed	0.5
Spanish lime	2.0
Spearmint, tops	30
Spice Subgroup 19B, except black pepper	38
Star apple	2.0
Starfruit	2.0
Sugar apple	2.0
Sugarcane, cane	0.2
Sunflower subgroup 20B	0.5
Tamarind	2.0
Tomato, paste	0.6
Tomato subgroup 8–10A	0.2
Turnip, greens	25
Vegetable, cucurbit, group 9	0.3
Vegetable, foliage of legume, group 7	30.0
Vegetable, leafy, except brassica, group 4	30.0
Vegetable, leaves of root and tuber, group 2	50.0
Vegetable, legume, edible podded, subgroup 6A, except soybean	3.0
Vegetable, root, subgroup 1A	0.5
Vegetable, tuberous and corm, subgroup 1C	8.0
Wasabi, dry	260
Wasabi, fresh	50
Watercress	3.0
Wax jambu	2.0
Wheat, bran	0.20
Wheat, forage	25
Wheat, grain	0.10
Wheat, hay	15
Wheat, straw	4.0

*2.0 (of which not more than 0.1 is contained in the pulp)

* * * * *

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