that time,'' the EPA explained, states ''may also begin applying EPA's interpretations to the extent they do not conflict with their approved SIPs.'' *Id.* We now believe it is likely that state and local permitting authorities would have understood this straightforward explanation.

Further, as previously discussed, determining whether a source has sought to circumvent NSR by failing to treat nominally-separate activities as a single project is inherently case-specific and fact-dependent. Given this, it is not reasonable to imagine that perfect clarity could ever be achieved. To the extent, however, that the 2009 NSR Aggregation Action, in setting forth both the ''substantially related'' interpretation and the EPA's policy for applying that interpretation, provides some meaningful guidance to sources and to state and local permitting authorities, we fail to understand how revoking the 2009 NSR Aggregation Action would serve to promote clarity.

Indeed, in this regard, we believe in most cases that sources and state and local air agencies already implement a standard that is similar to the substantially related standard. To the extent that a state or local air agency desires to formally adopt the 2009 NSR Aggregation Action, the EPA will provide support to those agencies to process SIP submittals and issue approvals, as warranted. In most cases, however, we do not think changes in state plans would be needed to implement this interpretation.

C. Completing the Reconsideration Proceeding

We believe that this final action addresses the concerns raised by the petitioner with respect to the 2009 NSR Aggregation Action—*e.g.,* adequate notice and logical outgrowth, the legal underpinnings of the action, state adoption, and our need to change or clarify our aggregation policy. Accordingly, this action concludes the reconsideration proceeding of the 2009 NSR Aggregation Action.

D. Lifting the Administrative Stay; Announcement of Effective Date

On May 18, 2010, after a series of temporary administrative stays of the 2009 NSR Aggregation Action, the EPA exercised the provisions of the APA section 705 to postpone the effectiveness of the action ''until judicial review is no longer pending or the EPA completes the reconsideration process.'' 75 FR 27644. Since this action concludes the reconsideration proceeding, and we have affirmed the legal consistency and policy appropriateness of the 2009 NSR Aggregation Action, we are hereby lifting the indefinite administrative stay and announcing the effective date of the action. The effective date of the 2009 NSR Aggregation Action, published in the **Federal Register** on January 15, 2009 (74 FR 2376), and delayed on February 13, 2009 (74 FR 7284), May 14, 2009 (74 FR 22693), and May 18, 2010 (75 FR 27643), begins again on November 15, 2018.

IV. Environmental Justice Considerations

We believe that this action does not have any effect on environmental justice communities. Through this action, the EPA is affirming its interpretation that its current NSR regulations allow for the 2009 NSR Aggregation Action and, as such, no increased burden is expected for source owners, permitting authorities, or environmental justice communities.

V. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

VI. Judicial Review

Section 307(b)(1) of the CAA indicates which Federal Courts of Appeal have venue for petitions of review of final agency actions by the EPA under the CAA. This section provides, in part, that petitions for review must be filed in the U.S. Court of Appeals for the District of Columbia Circuit (i) when the agency action consists of ''nationally applicable regulations promulgated, or final actions taken, by the Administrator'' or (ii) when such action is locally or regionally applicable, if ''such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.''

This action completes the reconsideration proceeding and makes effective the 2009 NSR Aggregation Action. The 2009 NSR Aggregation Action is an interpretation of NSR rule language that applies in every state and territory in the United States where EPA is the permitting authority. Therefore, to the extent that this action is a ''final action,'' it is ''nationally applicable'' within the meaning of CAA section 307(b)(1).

Under section 307(b)(1) of the Act, to the extent that this action is judicially reviewable, petitions for judicial review of this action must be filed in the United States Court of Appeals for the District of Columbia Circuit by January 14, 2019.

VII. Statutory Authority

The statutory authority for this action is provided by section 301(a) of the CAA as amended (42 U.S.C. 7601(a)). This document is also subject to section 307(d) of the CAA (42 U.S.C. 7407(d)).

Dated: November 7, 2018.

Andrew R. Wheeler,

Acting Administrator.

[FR Doc. 2018–24820 Filed 11–14–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0744; FRL–9985–45]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of azoxystrobin in or on beet, sugar, roots and vegetable, root, except sugar beet, subgroup 1B. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 15, 2018. Objections and requests for hearings must be received on or before January 14, 2019, 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–2017–0744, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0744 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 January 14, 2019. 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–2017–0744, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 6, 2018 (83 FR 9471) (FRL–9973–27), 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 7F8590) by Syngenta Crop Protection, LLC, 18300 Greensboro Road, NC. The petition requested that 40 CFR 180.507 be amended by establishing tolerances for residues of the fungicide azoxystrobin, in or on beet, sugar, roots at 5.0 parts per million (ppm) and vegetable, root, subgroup 1B at 0.5 ppm. The petition also requested that the tolerance for vegetable, root, subgroup 1A be removed once these new tolerances are established. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing the tolerance level for vegetable, root, subgroup 1B at 1.0 ppm instead of 0.5 ppm. Additionally, the Agency has revised the commodity name to vegetable, root, except sugar beet, subgroup 1B. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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.

With repeated dosing by the oral route, the liver and bile ducts were consistently affected by azoxystrobin. Liver and biliary effects were seen in rats (increased liver weights, gross and histopathological lesions of the bile duct and liver), and in dogs (increased liver weights, clinical observations including fluid feces and salivation) and clinical chemistry alterations (including increased serum levels of alkaline phosphatase, and gamma-glutamyl transferase; and decreases in serum albumin). The effects seen are indicative of changes to liver/biliary function. Decreased body weight (rats and mice)

and decreased body weight gain (rats and rabbits) were also consistent findings across studies and species. Other effects including decreased food intake/utilization, increased diarrhea and other clinical toxicity observations such as urinary incontinence, salivation, hunched postures and distended abdomens were also seen in various studies (developmental toxicity, reproduction, and 90-day oral toxicity) in rats. Inhalation exposure to a soluble-concentrate (SC) formulation of azoxystrobin resulted in adverse microscopic changes in the nasal cavity and larynx.

No developmental effects were seen in the rabbit and rat developmental toxicity studies and no reproductive or offspring effects were seen in the 2-generation rat reproduction study. In the reproduction study, decreased body weights and increased adjusted liver weights were observed at the same dose in both offspring and parental animals. Therefore, the toxicity data showed no increased susceptibility in the young.

In the acute and subchronic neurotoxicity studies, there were no consistent indications of treatment-related neurotoxicity. There was no evidence of neurotoxicity seen in the acute neurotoxicity study in rats from a single gavage dose up to 2,000 mg/kg. There was also no evidence of neurotoxicity seen in the subchronic neurotoxicity study in rats up to the highest dose tested (201 mg/kg/day). Based on the toxicity profile of azoxystrobin, a developmental neurotoxicity study in rats is not needed.

Although azoxystrobin induced a weak mutagenic response in the mouse lymphoma assay (non-linear, slight but significant increases in the mutation frequency of mouse lymphoma cells), the activity expressed *in vitro* is not expected to be expressed in whole animals. There was no evidence of carcinogenicity in rats and mice at acceptable tested dose levels; therefore, azoxystrobin is classified as ''not likely to be carcinogenic to humans''.

Azoxystrobin has a low order of acute toxicity via oral, dermal and inhalation routes of exposure. Azoxystrobin is not an eye or skin irritant and is not a skin sensitizer.

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 lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document Azoxystrobin: Human Health Risk Assessment for a New Post-Harvest Use on Sugar Beets and Amend the existing Vegetable, Root, Subgroup 1A to Vegetable, Root, Subgroup 1B (except Sugar Beets) at pages 11–18 in docket ID number EPA–HQ–OPP–2017–0744.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for azoxystrobin used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—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	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 two-hours post dose at all dose levels tested.
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.
Episodic granule ingestion (Children 1 to <2 years old).	LOAEL = 200 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 3x	Residential LOC for MOE = 300.	Acute Neurotoxicity—Rat. LOAEL = 200 mg/kg/day based on diarrhea at two-hours post dose at all dose levels tested.
Incidental oral short-term (1–30 days) (Intermediate-term (1–6 months)).	NOAEL = 35 mg/kg/day UF_A= 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	2-generation reproduction study—Rats. LOAEL = 165 mg/kg/day based on decreased pup weights in both males and females (↓8–21%).
Inhalation (All durations)	Inhalation study NOAEL = 3.8 μg/L (inhalation absorption rate = 100%). UF_A = 3x UF_H = 10x FQPA SF = 1x	LOC for MOE = 30	28-Day inhalation toxicity study in rats on SC formulation+. LOAEL = 12.2 μg/L based on adverse histopathological changes in the larynx (squamous metaplasia) and nasal cavity (metaplasia of the respiratory epithelium). There was an increase in severity with increases in the test concentrations.
Cancer (Oral, dermal, inhalation)	Azoxystrobin is classified as ''not likely to be carcinogenic to humans''.		

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 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 (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the acute dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM–FCID; version 3.16). The assessment is based on 100% of the 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.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the chronic dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM–FCID; version 3.16). The assessment was partially refined, and used tolerance-level residues for all commodities and average percent crop treated (PCT) estimates when available.

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 for the chronic dietary exposure assessment as follows: Almonds, 20%; apricots, 10%; artichokes, 20%; asparagus, <2.5%; barley, <2.5%; green beans, 15%; blueberries, 15%; broccoli, 10%; cabbage, 10%; caneberries, 5%; cantaloupes, 20%; carrots, 10%; cauliflower, <2.5%; celery, 10%; corn, <2.5%; cotton, <2.5%; cotton (seed treatment), 25%; cucumbers, 20%; dry beans/peas, <2.5%; eggplant, 30%; garlic, 70%; grapefruit, 20%; grapes, 5%; hazelnuts, 5%; lemons, <2.5%; lettuce, <2.5%; nectarines, <2.5%; onions, 5%; oranges, 5%; peaches, 5%; peanuts, 20%; peanuts (seed treatment), 30%; green peas, <2.5%; pecans, 5%; peppers, 20%; pistachios, 5%; plums/prunes, <2.5%; potatoes, 40%; potatoes (seed treatment), <1%; pumpkins, 20%; rice, 40%; soybeans, 5%; soybeans (seed treatment), <1%; spinach, 10%; squash, 20%; strawberries, 25%; sugar beets, 10%; sugar beets (seed treatment), <2.5%; sweet corn, 15%; tangelos, 25%; tangerines, 10%; tobacco, 15%; tomatoes, 25%; walnuts, <2.5%; watermelons, 15%; wheat, 5%; wheat seed (seed treatment), <1%. For crops not specified, 100 PCT was used.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figures for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Surface Water Concentration Calculator (SWCC) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of azoxystrobin for acute exposures are estimated to be 70.2 parts per billion (ppb) for surface water and 3.1 ppb for ground water. For chronic exposures for non-cancer assessments the EDWCs of azoxystrobin are estimated to be 48.5 ppb for surface water and 3.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 70.2 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 48.5 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: Conventional residential use on turf and ornamentals and antimicrobial uses as a materials preservative in paints and plastics. The proposed use will not result in additional residential exposures. Existing residential uses result in (1) short-term handler dermal and inhalation exposures for adults; (2) short-term post-application dermal exposures for adults, youth 11 to 16 years old, children 6 to 11 years old, and children 1 to <2 years old; and (3) short-term incidental oral exposures to children 1 to <2 years old. Since the effects from inhalation exposure differ from effects from oral exposure, the residential handler exposures are not aggregated with dietary exposures. No hazard was identified for dermal exposure. The Agency's assessment of risk aggregates residential exposure from hand-to-mouth incidental oral exposures to children 1 to <2 years old from preserved vinyl flooring.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA 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 website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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.* No developmental effects were seen in the rabbit and rat developmental toxicity studies, and no reproductive or offspring effects were seen in the 2-generation rat reproduction study. In the reproduction study, decreased body weights and increased adjusted liver weights were observed at the same dose in both offspring and parental animals. Therefore, the toxicity data showed no increased susceptibility in the young.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all exposure scenarios except acute exposure and episodic granule ingestion. For assessing acute dietary risk and episodic oral ingestion of granules, EPA is retaining an FQPA factor of 3X to account for the use of a LOAEL from the acute neurotoxicity study to derive an acute reference dose. 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 LOAEL is based on a transient effect (diarrhea in rats) expected to be relatively insignificant in nature. This effect is also seen in other chemicals of the same class.
- The diarrhea was only seen in studies using gavage dosing in the rat, but not in studies using repeat dosing through dietary administration in rats or mice, and not through gavage dosing in rabbits.
- The very high dose level needed to reach the acute oral lethal dose $(LD)_{50}$ (>5,000 mg/kg), and the overall low toxicity of azoxystrobin.

The decision to reduce the FQPA safety factor to 1X for the assessment of the remaining exposure scenarios is based on the following findings:

i. The toxicity database for azoxystrobin is considered sufficient for selecting toxicity endpoints and PODs for risk assessment.

ii. There is no indication that azoxystrobin is a neurotoxic chemical. There was no evidence of neurotoxicity seen in the acute neurotoxicity study in rats from a single gavage dose up to 2,000 mg/kg. There was also no evidence of neurotoxicity seen in the subchronic neurotoxicity study in rats up to the highest dose tested (201 mg/kg/day). Therefore, 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 in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. In the reproduction study, the offspring and the parental effects occurred at the same dose level.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary (food) exposure assessments utilized conservative upper-bound inputs including assuming 100% CT and tolerance-level residues for all 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 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.

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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to azoxystrobin will occupy 82% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to azoxystrobin from food and water will utilize 18% of the cPAD for children 1–2 years old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of 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 390 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). Because no intermediate-term adverse effect was identified, azoxystrobin is not expected to pose an intermediate-term risk. Therefore, the intermediate-term aggregate risk would be equivalent to the chronic dietary exposure estimate.

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 methodology (gas chromatography with nitrogen-phosphorus detector (GC/NPD) method, RAM 243/04) is available to enforce the tolerance expression for residues of azoxystrobin and its *Z*-isomer in crop commodities. This method (designated RAM 243, dated 5/15/98) has been submitted to FDA for inclusion in the Pesticide Analytical Manual (PAM, Volume II).

The method 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 established MRLs for azoxystrobin in or on root and tuber vegetables (except potato) at 1.0 ppm. This MRL is the same as the tolerance being established for azoxystrobin in the United States.

C. Response to Comments

EPA received ten comments to the docket EPA–HQ–OPP–2017–0744. However, only three comments were in response to the petition filed by Syngenta Crop Protection. One comment (ID: EPA–HQ–OPP–2017–0744–0007) among the three, is inclusive of the other two comments (ID: EPA–HQ–OPP–2017–0744–0008 and EPA–HQ–OPP–2017–0744–0009), and describes portions of the content of the **Federal Register** notice EPA published on March 6, 2018 (83 FR 9471), and expresses support for tolerances. The remaining seven comments were not germane to this action, therefore no further response from the Agency is required.

D. Revisions to Petitioned-For Tolerances

The Agency recommends increasing the tolerance for vegetable, root, except sugar beet, subgroup 1B from the proposed 0.5 ppm to 1.0 ppm to harmonize with the existing Codex MRL. Additionally, the Agency is revising the significant figure on root vegetables subgroup 1B based on current policy and revising the commodity definition to reflect the common commodity vocabulary currently used by the Agency. The commodity definition was revised from vegetable, root, subgroup 1B to vegetable, root, except sugar beet, subgroup 1B.

V. Conclusion

Therefore, tolerances are established for residues of azoxystrobin, in or on beet, sugar, roots at 5.0 ppm and vegetable, root, except sugar beet, subgroup 1B at 1.0 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and

Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: November 1, 2018.

Michael Goodis,

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. Remove the entry for ''Vegetable, root, subgroup 1A'' from the table in paragraph (a)(1).

■ b. Add alphabetically ''Beet, sugar, roots''; and ''Vegetable, root, except sugar beet, subgroup 1B'' to the table in paragraph (a)(1).

The additions read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Beet, sugar, roots	5.0
* * * * *	
Vegetable, root, except sugar beet, subgroup 1B	1.0
* * * * *	

* * * * *

[FR Doc. 2018–24974 Filed 11–14–18; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 160906822–7547–02]

RIN 0648–XG618

Snapper-Grouper Fishery of the South Atlantic; 2018 Commercial Closure for Hogfish in the Florida Keys/East Florida Area of the South Atlantic

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements accountability measures (AMs) for the hogfish commercial sector in the exclusive economic zone (EEZ) of the South Atlantic for the Florida Keys/East Florida (FLK/EFL) stock for the 2018 fishing year through this temporary rule. NMFS estimates commercial hogfish landings for the FLK/EFL hogfish stock for the 2018 fishing year will reach the annual catch limit (ACL) on November 16, 2018. Therefore, NMFS closes the commercial sector for the FLK/EFL hogfish stock in the South Atlantic EEZ on November 16, 2018, through the remainder of the 2018 fishing year. This closure is necessary to protect the hogfish resource in the FLK/EFL region of the South Atlantic.

DATES: This rule is effective 12:01 a.m., local time, November 16, 2018, until 12:01 a.m., local time, January 1, 2019.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes hogfish and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The final rule for Amendment 37 to the FMP established two stocks of hogfish in Federal waters of the South Atlantic and new stock boundaries under the jurisdiction of the South Atlantic Fishery Management Council (82 FR 34584; July 25, 2017). One stock is the Georgia through North Carolina