in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 30, 2015. 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 may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

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

Dated: April 14, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(458) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(458) New and amended regulations for the following APCDs were submitted on December 29, 2014 by the Governor's designee.

(i) Incorporation by Reference.

(A) South Coast Air Quality Management District.

(*1*) Rule 1325, Rule 1325, ''Federal $PM_{2.5}$ New Source Review Program'' adopted on December 5, 2014.

[FR Doc. 2015–10239 Filed 4–30–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0248; FRL–9926–24]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of azoxystrobin in or on coffee, green bean; pear, Asian; and tea, dried. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) to cover residues of azoxystrobin in coffee, Asian pear, and tea imported into the United States; there are currently no U.S. registrations for pesticides containing azoxystrobin that are used on coffee, Asian pear, or tea.

DATES: This regulation is effective May 1, 2015. Objections and requests for hearings must be received on or before June 30, 2015, 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–2014–0248, 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: Susan Lewis, 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 Publishing 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–2014–0248 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or

before June 30, 2015. 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–2014–0248, 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.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 23, 2014 (79 FR 29729) (FRL–9910–29), 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 3E8228) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide azoxystrobin, in or on coffee, bean, green at 0.03 parts per million (ppm); pear, Asian at 0.07 ppm and tea at 10 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the petitioner, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has increased the tolerance on tea from what the petitioner requested. The reason for this change is 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.

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. Repeated oral dosing 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, increase in alkaline phosphatase and gamma glutamyltransferase, decrease in albumin, and 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. Decreases in body weight and food utilization were noted in the rat subchronic neurotoxicity study. There were no 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. 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 lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Human Health Aggregate Risk Assessment for Permanent Tolerances on Imported Asian Pear, Imported Tea, and Imported Coffee; Establishment of Permanent Tolerances on Ti Palm and for Crop Group Conversions for Stone Fruits Group 12–12 and Tree Nut Group 14–12 Crop Groups'' on page 5 in docket ID number EPA–HQ–OPP–2014–0248.

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 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 = 0.67mg/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.
Incidental oral short-term (1 to 30 days) & intermediate-term (1 to 6 months)	NOAEL = 35 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	2-Generation Reproduction Study—Rat. LOAEL = 165 mg/kg/day based on decreased pup weights in both males and females (↓8–21%).
Dermal (All durations)	No hazard was identified for this exposure scenario.		21-Day Repeated Dose Dermal Study—Rat. No dermal or systemic toxicity was seen at the limit dose (1,000 mg/kg/day).
Inhalation [1] short-term (1 to 30 days) & intermediate-term (1 to 6 months)	NOAEL = 35 mg/kg/day [2]. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	2-Generation Reproduction Study—Rat. LOAEL = 165 mg/kg/day based on decreased pup weights in both males and females (↓8–21%).
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).

[1] To protect for the body weight decreases seen in the pups, a 69 kg body weight was used for estimating short- and intermediate-term inhalation doses because the pup body weight decrease also influenced by the maternal health.

[2] Toxicity via the inhalation route is assumed to be equivalent to the oral route.

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 assessment incorporated tolerance-level residues for all commodities except for citrus fruits (which used the highest residues from residue trials); 100 percent crop treated (PCT); and Dietary Exposure Evaluation Model (DEEM) (ver. 3.16) default processing factors, except for where tolerances were established for processed commodities or when processing studies showed no concentration. Field trial data were translated from the representative commodities to the non-representative commodities according to HED SOP 2000.1''Guidance for Translation of Field Trial Data from Representative Commodities in the Crop Group Regulation to other Commodities in Each Crop Group/Subgroup.''

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the chronic dietary analysis incorporated tolerance-level residues for all commodities, average PCT estimates when available and DEEM (ver. 3.16) default processing factors, except for where tolerances

were established for processed commodities or when processing studies showed no concentration.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that azoxystrobin should be classified as ''not likely'' to be carcinogenic to humans. Therefore a cancer risk assessment 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 the chronic dietary exposure assessment for existing uses as follows: Almonds, 20%; apricots, 10%; artichokes, 20%; asparagus, <2.5%; barley, <2.5%; green beans, 15%; blueberries, 15%; broccoli, 10%; cabbage, 10%; cane berries, 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%.

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 Screening Concentration in Ground Water (SCI–GROW) model and Pesticide Root Zone Model Ground Water (PRZM GW), for surface water, the estimated drinking water concentrations (EDWCs) of azoxystrobin for acute exposures are estimated to be 70.2 parts per billion (ppb) and for chronic exposures are estimated to be 48.5 ppb. For ground water, the estimated drinking water concentration for both acute and chronic exposure scenarios 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 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: 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).

The proposed uses do not impact the aggregate risk assessment; however, the scenarios that do impact the aggregate assessment have been re-evaluated in this assessment to reflect the revised incidental oral and inhalation PODs. Using those new PODs, EPA assessed residential exposure using the 2012 updated residential standard operating procedures (SOPs) that are now used in all human health assessments.

For the adult aggregate assessment, the Agency used inhalation exposure from adult handlers applying treated paint via airless sprayers; for the aggregate assessment for children, the Agency used post-application inhalation exposure from space-trays and hand-to-mouth exposures from indoor applications to treated carpets for children 1 to <2 years old.

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 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 includes prenatal developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in young rats. In these studies, there is no evidence that azoxystrobin results in increased quantitative sensitivity to developing fetuses. Also in the reproduction study, the offspring and the parental effects occurred at the same dose level.

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. For assessing acute dietary risk, 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 $(LD)_{50}$ (≤ 5000 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 complete.

ii. There is no indication that azoxystrobin is a neurotoxic chemical. Although clinical signs were observed in the acute and subchronic neurotoxicity studies which included transient diarrhea, decreased body weight, body weight gain, and food utilization, no other effects were seen in those studies that would be considered indicative of neurotoxicity. 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to azoxystrobin will occupy 40% 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 15% 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 2,400 for adults and 280 for children 1–2 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 a 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 a MRL for azoxystrobin in or on coffee, bean at 0.03 ppm. The US tolerance for coffee is harmonized with the Codex MRL. The Codex has not established a MRL for Asian pear or tea.

C. Response to Comments

One comment was received in response to the notice of filing of Syngenta Crop Protection's petition. The commenter objected to the increase of chemical residues generally and expressed additional concerns about the carcinogenic effects of chemicals in general on humans. The Agency understands the commenter's concerns regarding toxic chemicals and their potential effects on humans. Pursuant to its authority under the FFDCA, and as discussed further in this preamble, EPA conducted a comprehensive assessment of azoxystrobin, which included an assessment on the carcinogenic potential of azoxystrobin. Based on its assessment of the available data, the Agency has concluded that azoxystrobin is not likely to be a carcinogen and that there is a reasonable certainty that no harm will result from aggregate exposure to residues of azoxystrobin.

D. Revisions to Petitioned-For Tolerances

The tolerance on tea has been revised from what was proposed in the initial petition. EPA is increasing the proposed tolerance for tea from 10 ppm to 20.0 ppm. The proposed tolerance of 10 ppm for tea is insufficient, as the trials were conducted at 50% of the label maximum rate. Correction by proportionality to the maximum label rate provides a tolerance recommendation of 20.0 ppm. Also, because magnitude of residue data used to determine the appropriate tolerance level were provided for dried tea only, EPA is only establishing a tolerance for dried tea at this time.

In addition, EPA is altering the commodity name for ''coffee, green bean'' from the petitioned-for name (''coffee, bean, green'') to be consistent with the general food and feed commodity vocabulary EPA uses for tolerances and exemptions.

V. Conclusion

Therefore, tolerances are established for residues of azoxystrobin, in or on coffee, green bean at 0.03 ppm; pear, Asian at 0.07 ppm; and tea, dried at 20.0 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). 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: April 23, 2015.

Susan Lewis,

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. Add alphabetically the entries for ''Coffee, green bean''; [1] ''Pear, Asian'',[1] ''Tea, dried'' [1] to the table in paragraph (a)(1).

■ b. Revise footnote [1] at the end of the table in paragraph (a)(1).

The additions and revision read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Coffee, green bean [1]	0.03
* * * * *	
Pear, Asian [1]	0.07
* * * * *	
Tea, dried [1]	20.0

Commodity	Parts per million
* * * * *	

[1] There are no United States registrations for use of azoxystrobin on coffee, green bean; ginseng; pear, Asian and tea, dried.

* * * * *

[FR Doc. 2015–10149 Filed 4–30–15; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2015–0001; Internal Agency Docket No. FEMA–8381]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *http://www.fema.gov/fema/csb.shtm.*

DATES: The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Bret Gates, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4133.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are