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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0727; FRL-9966-09]

Fluoxastrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluoxastrobin in or on multiple commodities which are identified and discussed later in this document. Arysta LifeScience North America, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2015-0727, 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-2015-0727 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2015-0727, 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 16, 2016 (81 FR 14030) (FRL-9942-86), 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 5F8406) by Arysta LifeScience North America, LLC, 15401 Weston Parkway, Suite 150, Cary, North Carolina, 27513. The petition requested that 40 CFR 180.609 be amended by establishing tolerances for residues of the fungicide fluoxastrobin, (1*E*)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl] (5,6-dihydro-l,4,2-dioxazin-3-yl)methanone *O*-methyloxime,

and its Z isomer, (1*Z*)-[2-[[6-(2chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl] (5,6-dihydro-l,4,2-dioxazin-3-yl)methanone *O*-methyloxime, in or on avocado at 0.9 parts per million (ppm); barley, grain at 0.4 ppm; barley, hay at 15 ppm; barley, straw at 15 ppm; rapeseed subgroup 20A at 0.8 ppm; and dried shelled pea and bean (except soybean) subgroup 6C at 0.2 ppm. No comments were submitted on this notice of filing.

Based on data submitted with the petition, the tolerances established by the Agency in this action differ slightly from what the petitioner requested. The reasons for these deviations are discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other

relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluoxastrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluoxastrobin 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.

In mammals, the liver and kidney were the main target organs. Liver effects (cholestasis) were observed in dogs following subchronic and chronic oral exposures. Dogs were the more sensitive species, with liver effects in dogs occurring at a 35-fold lower dose than elicited adverse effects in other species. Kidney effects were observed in rats and dogs following subchronic exposures, but not following chronic exposures. In rats, effects were also observed in the adrenal glands, urinary bladder, and urethra. There were dose-related changes in the liver and kidneys of mice, however, the changes were not considered to be adverse.

There was no evidence of increased quantitative or qualitative fetal or offspring susceptibility in the developmental toxicity studies in rats or rabbits or the two-generation reproduction toxicity study in rats. There were no maternal or developmental effects in the rat developmental study. In the developmental toxicity study in rabbits, maternal

effects (cold ears, transient body-weight loss, and decreased food consumption) occurred in the absence of fetal toxicity. In the two-generation reproduction study in rats, offspring effects (decreased body weights, delayed preputial separation, and incomplete ossification) occurred at the same dose as parental toxicity (decreased premating absolute body weight and body-weight gain).

Fluoxastrobin has low acute toxicity via the oral, dermal, and inhalation routes of exposure. Overall, it is mildly irritating to the eyes, but is neither a dermal irritant nor a dermal sensitizer. There were no signs of neurotoxicity or immunotoxicity in the database. Fluoxastrobin is classified as "Not Likely to be Carcinogenic to Humans" based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies. There was no concern for mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by fluoxastrobin 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 Risk Assessment in Support of Application to Avocado, Barley, Rapeseed subgroup 20A, and Dried Shelled Pea and Bean* on pages 14 and 15 in docket ID number EPA-HQ-OPP-2015-0727.

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 fluoxastrobin used for human risk assessment is shown in the Table of this unit.

Table - Summary of Toxicological Doses and Endpoints for fluoxastrobin 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)	No appropriate toxicological effect attributable to a single dose was observed. Therefore, a dose and endpoint were not		

	identified for this risk assessment		
Chronic dietary (All populations)	NOAEL= 1.5 mg/kg/day UF_A = 10x UF_H = 10 x FQPA SF = 1x	Chronic RfD = 0.015 mg/kg/day cPAD = 0.015 mg/kg/day	Chronic Toxicity Study in Dogs LOAEL = M/F 8.1/7/7 mg/kg/day based on body weight reductions and hepatocytomegaly and cytoplasmic changes associated with increased serum liver alkaline phosphatase indicative of cholestasis.
Incidental oral short-term (1-30 days) and Intermediate-term (1-6 months)	NOAEL= 3.0 mg/kg/day UF_A = 10x UF_H = 10 x FQPA SF = 1x	LOC for MOE = <100	90-Day Toxicity in Dogs LOAEL = 24 mg/kg/day based on reductions in body-weight gain and food efficiency, liver effects (cholestasis), and kidney effects (increased relative weights in females, degeneration of proximal tubular epithelium in males).
Dermal short-term (1-30 days) and intermediate-term (1 - 6 months)	Oral study NOAEL = 3.0 mg/kg/day (dermal absorption rate = 2.3% UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = <100 Occupational LOC for MOE = <100	90 Day Toxicity in Dog LOAEL = 24 mg/kg/day based on reductions in body-weight gain and food efficiency, liver effects (cholestasis), and kidney effects (increased relative weights in females, degeneration of

			proximal tubular epithelium in males).
Inhalation short and Intermediate-Term	Oral study NOAEL= 3.0 mg/kg/day (inhalation toxicity is considered equivalent to oral toxicity) UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = <100 Occupational LOC for MOE = <100	90-Day Toxicity in Dogs LOAEL = 24 mg/kg/day based on reductions in body-weight gain and food efficiency, liver effects (cholestasis), and kidney effects (increased relative weights in females, degeneration of proximal tubular epithelium in males).
Cancer (Oral, dermal, inhalation)	Classification: Fluoxastrobin is classified as "not likely to be carcinogenic to humans" based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_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 fluoxastrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing fluoxastrobin tolerances in 40 CFR 180.609. EPA assessed dietary exposures from fluoxastrobin 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. No such effects were identified in the toxicological studies for fluoxastrobin; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID, Version 3.16, food consumption data from the 2003-2008 U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues for livestock commodities, average field trial residues for some crop commodities, and percent crop treated (PCT) and percent crop treated for new use (PCTn) estimates for some commodities. DEEM version 7.81 default processing factors were assumed, except for tolerances that 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 fluoxastrobin 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 the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-

ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows: corn, 1.0%; peanuts, 2.5%; peppers, 2.5%; potatoes, 1.0%; soybeans, 1.0%; and wheat, 2.5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), and proprietary market surveys for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis and maximum PCT for acute

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 2.5%. The maximum PCT figure is the highest observed maximum value reported within the most recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except for situations in which the maximum PCT is less than 2.5%. In cases where the estimated value is less than 2.5% but greater than 1%, the average and maximum PCT used are 2.5%. If the estimated value is less than 1%, 1% is used as the average PCT and 2.5% is used as the maximum PCT.

The Agency estimated the PCT for new uses as follows: avocado, 12%; barley, 16%; canola, 9%; and dry beans/peas, 14%.

EPA estimates percent crop treated for new uses (PCTn) of fluoxastrobin based on the PCT of the dominant pesticide (i.e., the one with the greatest PCT) used on that crop over the three most recent years of available data. Comparisons are only made among pesticides of the same pesticide types (i.e., the dominant fungicide on the crop is selected for comparison with a new fungicide). The PCTs included in the analysis may be for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is publicly available and does not have to be calculated from available data sources. When a specific use site is not surveyed by USDA/NASS, EPA uses proprietary market research data or other publicly available state data when 80% or more of the crop acreage is grown in that state and calculates the PCTn.

This estimated PCTn, based on the average PCT of the market leader, is appropriate for use in the chronic dietary risk assessment. This method of estimating a PCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial five years of actual use. The predominant factors that bear on whether the estimated PCTn could be exceeded are (1) the extent of pest pressure on the crops in question; (2) the pest spectrum of the new pesticide in comparison with the market leaders as well as whether the market leaders are well-established for this use; and (3) resistance concerns with the market leaders. EPA has examined the relevant data and determined that it is unlikely that the actual PCT with fluoxastrobin on avocado, barley, canola (rapeseed subgroup 20A) and dried shelled pea and bean (crop subgroup 6C) will exceed the PCTn within the next five years.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT and PCTn 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 fluoxastrobin 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 fluoxastrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluoxastrobin. 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*.

The estimated drinking water concentrations (EDWCs) in surface water resulting from the proposed fluoxastrobin uses were calculated using the pesticide water calculator (PWC). Groundwater EDWCs for fluoxastrobin were derived for the proposed and existing uses using PRZM-Groundwater (PRZM GW). Based on PRZM GW, the EDWCs of fluoxastrobin for chronic exposures for non-cancer assessments are estimated to be 47.8 ppb for surface water and 182 ppb for ground water. The more conservative modeled estimate of drinking water concentrations (182 ppb) was directly entered into the dietary exposure model to assess the contribution to drinking water and chronic dietary risk.

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).

Fluoxastrobin is currently registered for the following uses that could result in residential exposures: broadcast control of diseases on turf, including lawns and golf courses. EPA assessed residential exposure using the following assumptions:

i. *Residential Handler Exposure*: All registered fluoxastrobin product labels with residential use sites (e.g., turf and ornamentals) require that handlers wear specific clothing (e.g., long sleeve shirt/long pants) and/or use personal-protective equipment (PPE). Therefore, the Agency has made the assumption that these products are not intended for homeowner use, and has not conducted a quantitative residential handler assessment.

ii. *Residential Post-Application Exposure*: Adults and children performing physical activities on turf and ornamentals during post-application activities (e.g., high-contact lawn activities, mowing, and gardening) may receive dermal exposure to fluoxastrobin residues. Young children 1 to <2 years old may also receive incidental oral post-application exposure to fluoxastrobin from treated turf. Residential post-application exposure is expected to be short-term in duration. Intermediate-term exposures are not likely because of the intermittent nature of exposure to homeowners. Post-application dermal and hand-to-mouth exposure scenarios were combined for children 1 < 2 years old. This combination was considered a protective estimate of children's exposure. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.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 fluoxastrobin to share a common mechanism of toxicity with any other substances, and fluoxastrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluoxastrobin 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 Food Quality Protection Act Safety Factor (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*. As discussed in Unit III.A., there is no evidence of quantitative or qualitative fetal or offspring susceptibility in the developmental toxicity studies in rats or rabbits nor in two-generation reproduction studies in rats.

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. That decision is based on the following findings:

i. The toxicity database for fluoxastrobin is complete.

ii. There is no indication that fluoxastrobin is a neurotoxic chemical, and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

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

iv. There are no residual uncertainties identified in the exposure databases. A partially refined chronic aggregate dietary (food and drinking water) exposure and risk assessments were conducted. The assumptions of the dietary assessment include tolerance-level residues for livestock commodities, average field-trial residues for some crop commodities, and PCT and PCTn estimates for some commodities. EPA made

conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluoxastrobin 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 fluoxastrobin.

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. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fluoxastrobin is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluoxastrobin from food and water will utilize 31% of the cPAD for the general U.S population and 77% of the cPAD for all infants <1-year-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 fluoxastrobin 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). Fluoxastrobin 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 fluoxastrobin.

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 150 for adults and 100 for children (1-2 years old). The Agency does not have concern if the MOEs are equal to or greater than 100. Furthermore, many conservative assumptions were incorporated into the assessment, so the actual exposure and risk are likely to be considerably lower than the estimates in the Agency assessment.

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

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluoxastrobin 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 fluoxastrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/ mass spectrometry) is available to enforce the tolerance expression. Method No. 00604 is available for plant commodities and Method No. 00691 is available for livestock commodities. 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 not established a MRL for fluoxastrobin.

C. Revisions to Petitioned-For Tolerances

EPA is establishing tolerance levels for the following commodities that differ from what the petitioner requested: avocado from 0.9 ppm to 1.0 ppm; barley, grain from 0.4 ppm to 0.40 ppm; rapeseed subgroup 20A from 0.8 ppm to 0.70 ppm; pea and bean, dried shelled, except soybean, subgroup 6C from 0.2 ppm to 0.20 ppm. The tolerances for avocado and rapeseed subgroup 20A differ because the Agency used different inputs for determining those tolerance levels. Although the petitioner and the Agency both used the Organization for Economic Co-operation and Development (OECD) calculation procedures to obtain tolerance levels, the Agency determined that some of the trials were not independent. In addition, if a higher residue value was observed at a preharvest interval (PHI) longer than the minimum labeled PHI, then the Agency used the highest value.

The Agency added a significant figure to the tolerances for barley, grain and pea and bean, dried shelled, except soybean to conform to current Agency policy on significant figures. In addition, the Agency has modified the commodity definition for dried shelled pea and bean (crop subgroup 6C) to pea and bean, dried shelled, except

soybean, subgroup 6C in order for consistency with the Agency's food and feed commodity vocabulary.

V. Conclusion

Therefore, tolerances are established for residues of fluoxastrobin, and its Z-isomer in or on avocado at 1.0 ppm; barley, grain at 0.40 ppm; barley, hay at 15 ppm; barley, straw at 15 ppm; rapeseed subgroup 20A at 0.70 ppm; and pea and bean, dried shelled, except soybean, subgroup 6C at 0.20 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: August 31, 2017.

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 § 180.609, add alphabetically "avocado", "barley, grain"; "barley, hay"; "barley, straw"; "pea and bean, dried shelled, except soybean, subgroup 6C"; and "rapeseed, subgroup 20A" to the table in paragraph (a)(1) to read as follows:

§ 180.609 Fluoxastrobin; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
Avocado	1.0
Barley, grain	0.40
Barley, hay	15
Barley, straw	15
****	***
Pea and bean, dried shelled, except soybean, subgroup 6C	0.20
****	***
Rapeseed, subgroup 20A	0.70
****	***

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[FR Doc. 2017-21113 Filed: 9/29/2017 8:45 am; Publication Date: 10/2/2017]