Dated: July 29, 2019.

L.M. Littlejohn,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0140; FRL–9996–79]

Fluoxastrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluoxastrobin in or on cotton, undelinted seed and cotton, gin byproducts. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 6, 2019. Objections and requests for hearings must be received on or before October 7, 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–2018–0140, 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–2018–0140 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 October 7, 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–2018–0140, 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 June 14, 2018 (83 FR 27744) (FRL–9978–29), 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 7F8649) by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. 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-pyrimidinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone *O*-methyloxime, in or on cotton, undelinted seed and cotton, gin byproducts at 0.01 parts per million (ppm). There were no comments received in response to the notice of filing.

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 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 study in the rats or rabbits and two-generation reproduction toxicity study in rats. In the two-generation reproduction study in rats, the only effects observed were in both the offspring and the parental animals at the same dose. No developmental effects were observed in the rat and rabbit developmental studies.

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. Fluoxastrobin has been classified by the Cancer Assessment Review Committee (CARC) 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 the NOAEL and the LOAEL are identified. 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 Table 1 of this unit.

TABLE 1—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 = 10X 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 = 10X 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 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).

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUOXASTROBIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Inhalation short 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.		

Note: 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 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, 1.0%; peppers, 1.0%; 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), 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 estimated the PCT for new uses as follows: Avocado, 12%; barley, 16%; canola, 9%; and dry beans/peas, 15%. EPA estimates 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 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 53.1 parts per billion (ppb) for surface water and 163 ppb for ground water. The more conservative modeled estimate of drinking water concentrations (163 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: Turf and ornamentals. 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 to <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 *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 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 uncertainty factors (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 2-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 this dietary assessment include tolerance-level residues for livestock and some crop commodities, average field-trial residues for some crop commodities, and PCT plus 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 postapplication 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 28% of the cPAD for the general U.S. population and 71% 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 160 for adults and 100 for children (1–2 years old). Because EPA's level of concern for fluoxastrobin is an MOE below 100, 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 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 methods with tandem mass-spectroscopy detection (LC/MS/MS) is available to enforce the tolerance expression. 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 in/on cotton.

V. Conclusion

Therefore, tolerances are established for residues of fluoxastrobin, (1*E*)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone *O*-methyloxime, in or on cotton, undelinted seed and cotton, gin byproducts at 0.01 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: July 23, 2019.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.609(a)(1), amend the table by adding alphabetically the commodities ''Cotton, gin byproducts'' and ''Cotton, undelinted seed'' to read as follows:

§ 180.609 Fluoxastrobin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Cotton, gin byproducts	0.01
Cotton, undelinted seed	0.01
* * * * *	

* * * * *

[FR Doc. 2019–16322 Filed 8–5–19; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02]

RIN 0648–XT010

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; inseason quota transfer.

SUMMARY: NMFS is transferring 15 metric tons (mt) of Atlantic bluefin tuna (BFT) quota from the Reserve category to the Harpoon category. With this transfer, the adjusted Harpoon category quota for the 2019 fishing season is 91 mt. The 2019 Harpoon category fishery is open until November 15, 2019, or until the Harpoon category quota is reached, whichever comes first. The action is based on consideration of the regulatory determination criteria regarding inseason adjustments, and applies to Atlantic tunas Harpoon category (commercial) permitted vessels.

DATES: Effective August 1, 2019, through November 15, 2019.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin, 978–281–9260, or Larry Redd, 301–427–8503.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in Amendment 7 to the 2006 Consolidated Atlantic Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (Amendment 7) (79 FR 71510, December 2, 2014), and in accordance with implementing regulations. NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.