ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0530; FRL–9985–23]

Trifloxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of trifloxystrobin in or on flax seed and amends an existing tolerance for aspirated grain fractions. Bayer CropScience requested these tolerances and amendments under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 15, 2019. Objections and requests for hearings must be received on or before April 16, 2019, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0530, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0530 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 April 16, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0530, 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 February 27, 2018 (83 FR 8408) (FRL–9972–17), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 7F8595 and 7F8633) by Bayer CropScience LP2, T.W. Alexander Dr., Research Triangle Park, NC 27709. The petitions requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide trifloxystrobin in or on flax, seed at 0.4 parts per million (ppm) (7F8595) and requested an amendment of the existing tolerance in or on grain, aspirated fractions from 5.0 ppm to 15 ppm (7F8633). That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the commodity definitions and tolerance values. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for trifloxystrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with trifloxystobin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

With repeated dosing, the liver is consistently the target organ for trifloxystrobin. Liver effects characterized by an increase in liver weights and an increased incidence of hepatocellular hypertrophy and/or hepatocellular necrosis were seen in rats, mice, and dogs. The effects of reduced body weights and food consumption were also found in the majority of the toxicity studies. Intestinal disturbances, as indicated by diarrhea and vomiting, were seen in dogs and rats at higher dose levels relative to those which caused liver and body weight effects. This finding was consistent with those produced by other members of the strobilurin class.

In the rabbit developmental toxicity study, an increase in the incidence of fused sternabrae was seen at a dose (500 mg/kg/day) 10 times higher than the maternal LOAEL (50 mg/kg/day). No developmental toxicity was seen at the limit dose (1,000 mg/kg) in the rat developmental toxicity study, but decreased body weight and food consumption was found in the maternal animals at 100 mg/kg/day or above. In the rat reproduction study, both parent and offspring showed decreases in body weight during lactation at similar dose levels (55.3 mg/kg/day). Therefore, there is no evidence of a qualitative or quantitative increase in sensitivity in the fetuses and pups of the developmental and reproduction studies, respectively. Trifloxystrobin was determined not to be carcinogenic in mice or rats following long-term dietary administration. Mutagenicity testing was positive in Chinese Hamster V79 cells at cytotoxic dose levels but negative in the remaining mutagenicity studies.

Trifloxystrobin was not neurotoxic in the acute neurotoxicity study, nor in any of the repeated dose studies in the available data. The requirement for a subchronic neurotoxicity study was waived because there is no evidence of neurotoxicity in the existing trifloxystrobin database or that of other strobilurin pesticides, and there are no neurotoxicity concerns for trifloxystrobin. However, a subchronic inhalation toxicity study is required for trifloxystrobin at this time.

Specific information on the studies received and the nature of the adverse effects caused by trifloxystrobin 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 the document titled ''*Trifloxystrobin. Human Health Risk Assessment for the Proposed New Use on Flax Seed and Increase of Established Tolerance on Aspirated Grain Fractions*'' on pages 28–30 in docket ID number EPA–HQ–OPP–2017–0530.

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 trifloxystrobin used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TRIFLOXYSTROBIN 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 (Females 13–50 years of age).	NOAEL = 250 mg/kg/day UF_A = 10x. UF_H = 10x FQPA SF = 1x	Acute RfD = 2.5 mg/kg/day. aPAD = 2.5 mg/kg/day	Developmental—Rabbit LOAEL = 500 mg/kg/day based on increased fetal skeletal malformation such as fused sternabrae.
Acute dietary (General population including infants and children).	There were no appropriate toxicological effects attributable to a single exposure (dose) observed in oral toxicity studies including maternal effects in developmental studies in rats and rabbits. Therefore, a dose and endpoint were not identified for this risk assessment.		

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TRIFLOXYSTROBIN 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
Chronic dietary (All populations)	NOAEL= 3.8 mg/kg/day UF_A = 10x. UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.038 mg/kg/day. cPAD = 0.038 mg/kg/day	Two-Generation Reproduction—Rat Maternal LOAEL = 55.3 mg/kg/day based on decreased body weight and histopathological lesions in the liver, kidney and spleen. Offspring LOAEL = 55.3 mg/kg/day based on decreased pup body weights during lactation.
Incidental oral short-term (1 to 30 days).	NOAEL= 3.8 mg/kg/day UF_A = 10x. UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Two-Generation Reproduction—Rat Maternal LOAEL = 55.3 mg/kg/day based on decreased body weight and histopathological lesions in the liver, kidney and spleen. Offspring LOAEL = 55.3 mg/kg/day based on decreased pup body weights during lactation.
Inhalation all durations	Oral study NOAEL= 3.8 mg/kg/day. UF_A = 10x UF_H = 10x UF_{DB} = 10x	LOC for MOE = 1000.	Two-Generation Reproduction—Rat Maternal LOAEL = 55.3 mg/kg/day based on decreased body weight and weight gain, decreased food consumption, liver, kidney and spleen effects. Offspring LOAEL = 55.3 mg/kg/day based on decreased pup body weights during lactation.
Cancer (Oral, dermal, inhalation).	Classification: ''Not likely to be Carcinogenic to Humans'' based on the absence of significant tumor increases 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_{DB} = to account for the absence of data or other data deficiency. 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 trifloxystrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing trifloxystrobin tolerances in 40 CFR 180.555. EPA assessed dietary exposures from trifloxystrobin 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 trifloxystrobin. In estimating acute dietary exposure, EPA used food consumption information from the 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 conducted an unrefined acute dietary assessment assuming tolerance-level residues for all crop commodities, with DEEM default processing factors. For ruminant and swine liver, and meat byproducts, a correction factor of 3x was applied to the tolerance to account for contribution of Metabolite L7a in these commodities (not applicable to kidney). All other livestock commodities used tolerance-level residues.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA conducted a partially refined chronic (food and drinking water) dietary assessment assuming average field trial residues for selected crops (subgroup 4–16A and 4–16B; subgroup 5–16; subgroup 13–07F; subgroups 19A and 19B; subgroups 22A and 22B; oranges; apples, and rice); all other crop commodities used tolerance-level residues. Percent crop treated (PCT) data were incorporated where available. Empirical and DEEM default processing factors were used. To account for contribution of Metabolite L7a, a 3x correction factor was applied to ruminant and swine liver, and meat byproducts (not applicable to kidney). All other livestock commodities used tolerance-level residues.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that trifloxystrobin 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 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 following average percent crop treated estimates were used in the chronic dietary risk assessment for the following crops for which trifloxystrobin is currently registered: Almonds: 5%, apples: 25%, apricots: 10%, artichokes: 25%, cantaloupes: 5%, carrots: 2.5%, celery: 20%, cherries: 25%, corn: <2.5%, cucumbers: <2.5%, dry beans/peas: <1%, grapefruit: 30%, grapes: 25%, hazelnuts: 65%, nectarines: 5%, oranges: 5%, peaches: <2.5%, peanuts: 5%, pears: 10%, pecans: 15%, peppers: 5%, pistachios: 10%, plums/prunes: <2.5%, potatoes: <1%, pumpkins: 5%, rice: 15%, soybeans: <2.5%, squash: <2.5%, strawberries: 5%, sugar beets: 5%, sweet corn: <2.5%, tangerines: 5%; tomatoes: <2.5%, walnuts: <2.5%, watermelons: 5%. 100% CT was assumed for the remaining commodities.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/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 one. 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%.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for trifloxystrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of trifloxystrobin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide in Water Calculator (PWC), the estimated drinking water concentrations (EDWCs) of trifloxystrobin for acute exposures are estimated to be 41 parts per billion (ppb) for surface water and 631 ppb for ground water; and for chronic exposures are estimated to be 28 ppb for surface water and 356 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 631 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 356 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).

Trifloxystrobin is currently registered for the following uses that could result in residential exposures: Turf and ornamentals. EPA assessed residential exposure using the following assumptions: Residential handler exposure and risk estimates from trifloxystrobin registrations were previously re-assessed in 2014 to reflect updates to the Agency's 2012 Residential SOPs along with policy changes for body weight assumptions. Since the 2014 assessment, it has been determined that all trifloxystrobin product labels with potential residential use sites require that handlers wear specific clothing (*e.g.,* long sleeve shirt/long pants) and use personal protective equipment (PPE). Therefore, EPA has made the assumption that trifloxystrobin products are not for homeowner use, and has not conducted a quantitative residential handler assessment at this time. Based upon the residential uses, adults and children performing physical post-application activities on turf (*e.g.,* golfing, mowing) or ornamentals (*e.g.,* activities in or around gardens or trees) may be exposed via dermal exposure to trifloxystrobin residues and children 1 to <2 years old may also be exposed via incidental oral post-application exposure to trifloxystrobin from treated turf. A dermal assessment was not conducted because an adverse systemic dermal hazard was not identified for trifloxystrobin. Therefore, the quantitative exposure/risk assessment for residential post-application exposures is based on incidental oral exposures from physical activities on turf (*i.e.,* for children 1 to <2 years old).

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 trifloxystrobin to share a common mechanism of toxicity with any other substances, and trifloxystrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that trifloxystrobin 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 (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no increased quantitative or qualitative susceptibility to trifloxystrobin in the developing or young animals as indicated by the results of the developmental studies in rat and rabbits and the 2-generation reproduction study 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 for all routes of exposure other than inhalation. The FQPA SF of 10x has been retained for

inhalation endpoints only to account for the lack of the subchronic inhalation toxicity study for trifloxystrobin at this time. This decision is based on the following findings:

i. The toxicity database for trifloxystrobin is complete with the exception of a subchronic inhalation toxicity study.

ii. There is no indication that trifloxystrobin 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 trifloxystrobin 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. The exposure databases are complete, and the exposure assessments will not underestimate the potential dietary (food and drinking water) or non-dietary exposures for infants and children from the use of trifloxystrobin. The chronic dietary food exposure assessment was partially refined based on average residues and PCT for some crops and conservative ground water drinking water modeling estimates. The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations, and are not likely to be exceeded. In addition, the residential post-application assessment is based upon the residential SOPs employing surrogate study data, as well as the use of a chemical-specific turf transferable residue study. The Residential SOPs are based upon reasonable ''worst-case'' assumptions and are not expected to underestimate risk. These data are reliable and are not expected to underestimate risk to adults or children.

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 trifloxystrobin will occupy 3.4% of the aPAD for females 13–49 years old, the only population group of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to trifloxystrobin from food and water will utilize 58% of the cPAD for all infants less than 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 trifloxystrobin 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).

Trifloxystrobin 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 trifloxystrobin.

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 an aggregate MOE of 120 for children 1 to less than 2 years old. Because EPA's level of concern for trifloxystrobin is a MOE of 100 or below, this MOE is not of concern.

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

An intermediate-term adverse effect was identified; however, trifloxystrobin 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 trifloxystrobin.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography method with nitrogen phosphorus detection (GC/NPD)) 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 trifloxystrobin in or on flax seed or aspirated grain fractions.

C. Response to Comments

Two comments were received to the Notice of Filing. One appeared to be related to the Department of Energy and stated in part that ''any environmentalist policy that would drive up the cost of energy, food, or other essential needs in the name of protecting nature must be rejected.'' This comment is not relevant to this action. A second comment stated in part ''Do not allow this toxic pesticide to be used anywhere in the world. Nobody needs this toxic chemical unleashed.''

Although the Agency recognizes that some individuals believe that pesticides

should be banned on agricultural crops, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these trifloxystrobin tolerances are safe. The commenter has provided no information supporting a contrary conclusion.

D. Revisions to Petitioned-For Tolerances

The Agency is establishing the tolerance value on flax seed as requested but with the addition of a significant figure based on current practice and establishing a tolerance on grain, aspirated fractions using the commodity definition that is consistent with common commodity vocabulary currently used by the Agency. Also, based upon the relevant field trial and processing studies, EPA is modifying the tolerance in/on aspirated grain fractions to 10 ppm, not 15 ppm as proposed by the registrant. This is due to differences in how the Agency and the registrant each calculated the processed commodity residues for aspirated grain fractions.

V. Conclusion

Therefore, a tolerance is established for residues of trifloxystrobin, including its metabolites and degradates, in or on flax, seed at 0.40 ppm, and the existing tolerance for grain, aspirated fractions is amended from 5.0 ppm to 10 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance and amends a tolerance 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: December 19, 2019.

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 § 180.555, add alphabetically the entry ''Flax, seed'' and revise the entry for ''Grain, aspirated fractions'' in the table in paragraph (a) to read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Flax, seed	0.40
* * * * *	
Grain, aspirated grain fractions	10
* * * * *	

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0420; FRL–9983–89]

Trifluralin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trifluralin in or on rosemary fresh leaves, rosemary dried leaves, and rosemary oil. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 15, 2019. Objections and requests for hearings must be received on or before April 16, 2019, and must