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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0514; FRL-9998-98]

Pyraflufen-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA)

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyraflufen-ethyl in or on multiple commodities which are identified and discussed later in this document. In addition, certain existing tolerances are removed as they are superseded by this action. Interregional Research Project Number 4 (IR-4) 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-2018-0514, 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 Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0514 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-2018-0514, 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 October 18, 2018, 83 FR 52787 (FRL-9984-21), 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 8E8684) by Interregional Research Project Number 4, IR-4 Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, New Jersey 08540. The petition requests the establishment of tolerances in 40 CFR 180.585 for residues of the herbicide pyraflufen-ethyl in or on the following commodities: cottonseed subgroup 20C at 0.04 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.01 ppm; fruit, stone, group 12–12 at 0.01 ppm; hop, dried cones at 0.02 ppm; nut, tree, group 14–12 at 0.01 ppm; tropical and subtropical, small fruit, edible peel, subgroup 23A at 0.01 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.02 ppm. Upon establishment of the above tolerances, the petitioner proposes to remove the existing tolerances for residues of pyraflufen-ethyl in or on cotton, undelinted seed at 0.04 ppm; fruit, stone, group 12 at 0.01 ppm; grape at 0.01 ppm; nut, tree, group 14 at 0.01 ppm; olive at 0.01 ppm; and pistachio at 0.01 ppm. That document referenced a summary of the petition prepared by Nichino America, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. 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 pyraflufen-ethyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyraflufen-ethyl follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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.

Pyraflufen-ethyl exhibits relatively low acute toxicity for oral, dermal, and inhalation exposure. It is moderately irritating to the eye but is not a skin irritant or a dermal sensitizer.

In repeat-dose oral studies, the liver, kidney, and hematopoietic system are the target organs for pyraflufen-ethyl in the rat and the mouse. Adverse effects were not noted in the dog following oral exposure nor in the rat following dermal exposure. There is no evidence of neurotoxicity following acute and subchronic dosing. In the submitted immunotoxicity study, an

immunosuppressant response was observed only at dose levels approaching the limit dose of 1,000 mg/kg/day. There was no evidence of increased susceptibility following pre-natal exposure to rats and rabbits in the developmental toxicity studies, nor following pre- and post-natal exposure to rats in the multi-generation reproduction study.

Pyraflufen-ethyl is classified as "Likely to be Carcinogenic to Humans" based on the presence of liver tumors (hepatocellular adenomas, carcinomas, and/or hepatoblastomas) in male and female mice. A linear low-dose extrapolation approach (Q_1* of 3.32 x 10^{-2} (milligram/kilogram/day (mg/kg/day))$^{-1}$) is used to estimate human cancer risk.

Specific information on the studies received and the nature of the adverse effects caused by pyraflufen-ethyl 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 "**SUBJECT: Pyraflufen-ethyl.** Human Health Risk Assessment for a Section 3 Registration of New Food Use on Hops and Conversions and Expansions of the Following Crop Groups: Nut, Tree, Group 14-12, Fruit, Stone, Group 12-12, Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit, Subgroup 13-07F, Vegetable, Tuberous and Corm, Subgroup lC, Tropical and Subtropical, Small Fruit, Edible Peel Subgroup 23A and Cottonseed Subgroup 20C" at pages 28-35 in docket ID number EPA-HQ-OPP-2018-0514.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to

determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for pyraflufen-ethyl used for human risk assessment is discussed in Unit III of the final rule published in the **Federal Register** of February 27, 2013 (78 FR 13257) (FRL-9379-6).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to pyraflufen-ethyl, EPA considered exposure under the petitioned-for tolerances as well as all existing pyraflufen-ethyl tolerances in 40 CFR 180.585. EPA assessed dietary exposures from pyraflufen-ethyl 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 pyraflufen-ethyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used

the food consumption data from the U.S. Department of Agriculture's (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA).

A highly refined chronic non-cancer exposure assessment was conducted. The Agency used residue estimates of 0.02 ppm for cottonseed oil (1/2 tolerance); residue values of ½ LOQ (limit of quantitation) (supported by field trial and monitoring data) for all other crops; and anticipated residues for livestock commodities calculated using updated dietary burdens based on field trial data for the livestock feed items. Percent crop treated (PCT) estimates and 2018 DEEM default processing factors were incorporated into the assessment.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that pyraflufen-ethyl should be classified as "Likely to be Carcinogenic to Humans" and a linear approach has been used to quantify cancer risk.

A linear low-dose extrapolation approach is used to estimate human cancer risk (Q1* of 3.32×10^{-2} (mg/kg/day)-1). The exposure inputs for the cancer assessment were quantified using the same estimates as discussed in Unit III.C.1.ii., *chronic exposure*, and a drinking water estimate of 0.672 ppb was used.

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, and 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 used the following average percent crop treated estimates for the chronic non-cancer and cancer analyses: 1% for barley, beans (snap, bush, pole, and string), celery, corn, dry beans and peas, onions, peanuts, pecans, potatoes, pumpkins, sorghum, soybeans, squash, sunflowers, tomatoes, and walnuts; 2.5% for almonds, apples, canola, cherries, lettuce, olive, and peach; 5% for cotton, garlic, table grape, raisin, kiwi, pistachio, plum and prune; 10% for wine grape, and pear; 20% for apricot, and fig; and 40% for pomegranate. For all other commodities, 100% crop treated was used.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for

the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT 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 up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which pyraflufen-ethyl 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 pyraflufen-ethyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyraflufen-ethyl. 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 Pesticide in Water Calculator (PWC version 1.52) was utilized to calculate all Estimated Drinking Water Concentrations (EDWCs). The EDWCs were incorporated directly into this dietary exposure assessment. Water residues were incorporated in the DEEM-FCID into the food categories "water, direct, all sources" and "water, indirect, all sources."

Drinking water concentrations were estimated separately for chronic and cancer durations. The highest EDWCs resulted from groundwater for these durations.

For chronic exposures for non-cancer assessments are estimated to be 0.295 ppb for surface water and 0.672 ppb for ground water. For chronic exposures for cancer assessments are estimated to be 0.268 ppb for surface water and 0.672 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For both chronic and cancer assessments, the highest EDWC of 0.672 ppb was used to assess the dietary contribution from 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).

Pyraflufen-ethyl is currently registered for use by residential and commercial applicators on

several residential/non-agricultural use sites; i.e., established ornamental turf lawns, parks, cemeteries, athletic fields, golf courses, sod farms, nurseries and ornamental plantings, and Christmas trees. There is the potential for residential (post-application) exposure pathways via the oral, dermal, and inhalation routes of exposure. Post-application dermal exposure (adults and children 1 to <2 years old) was not assessed for non-cancer effects since no toxicity was observed at the limit dose (1,000 mg/kg/day) in a 28-day dermal toxicity study in rats.

Residential exposure is expected to be short-term (1 to 30 days) in duration. The quantitative exposure assessment for residential non-cancer post-application exposures is based on incidental (hand-to-mouth) oral exposure (children 1 to <2 years old) from contact with residues on lawns and turf scenario. While not the only lifestage potentially exposed for these post-application scenarios, the lifestage that is included in the quantitative assessment is health protective for the exposures and risk estimates for any other potentially exposed lifestage. The registered application rate for pyraflufen-ethyl on lawns and turf was utilized in the assessing exposure.

A dermal and inhalation cancer exposure assessment was performed because dermal and inhalation exposure contributes to the overall cancer risk for pyraflufen-ethyl. 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 pyraflufen-ethyl to share a common mechanism of toxicity with any other substances, and pyraflufen-ethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyraflufen-ethyl does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with pyraflufen-ethyl. Developmental effects for both rats and rabbits occurred at either the same dose levels or were above the NOAELs and LOAELs for maternal toxicity. Similarly, there is no evidence of increased susceptibility of young rats in the pyraflufen-ethyl 2-generation rat reproduction study.

The NOAEL for offspring effects was identical to that of the parental animals. There are no residual uncertainties for pre- and/or postnatal exposure.

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 pyraflufen-ethyl is complete.

ii. There is no indication that pyraflufen-ethyl is a neurotoxic chemical based on results of acute and subchronic neurotoxicity studies, and no neurotoxic effect was seen in other toxicity studies. Therefore, there are no concerns for neurotoxicity and no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Developmental studies with pyraflufen-ethyl show no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure. Similarly, there is no evidence of increased susceptibility of young rats in the pyraflufen-ethyl 2-generation rat reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed using PCT data, where available; refined residue concentrations (generally ½ LOQ); anticipated residues in livestock commodities; and default and empirical processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyraflufen-ethyl in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of adults and children as well as incidental oral exposure of children. In addition, the residential exposure assessment used surrogate study data, including conservative exposure assumptions based on Day 0 dermal/oral contact to turf and surfaces treated at the maximum application rate. These

data are reliable and are not expected to underestimate risks 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.* 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, pyraflufen-ethyl 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 pyraflufen-ethyl from food and water will utilize <1% of the cPAD for the general U.S. population and all population subgroups, including children 1 to 2 years old, the most highly exposed population subgroup. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pyraflufen-ethyl 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). Pyraflufen-ethyl 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 pyraflufen-ethyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA concluded there is potential short-term exposure to pyraflufen-ethyl via dietary and residential exposure pathways. For adults, these pathways lead to exposure via oral and inhalation routes. EPA chose the most conservative scenario, children 1 to 2 years old with hand-to-mouth exposure from treated turf as well as the subpopulation with the highest chronic dietary exposure resulting in an aggregate MOE of 69,000. Because EPA's level of concern for pyraflufen-ethyl 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**,** pyraflufen-ethyl 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 pyraflufen-ethyl.

5. *Aggregate cancer risk for U.S. population*. The aggregate cancer risk assessment for the general U.S. population considers exposure estimates from dietary consumption of pyraflufen-ethyl in food and drinking water and exposure through residential uses of pyraflufen-ethyl. Exposures from residential uses are based on the lifetime average daily dose and assume an exposure period of 2 days per year and 35 years of exposure over a 78-year lifetime. Average food and water exposure to pyraflufen-ethyl was used in the aggregate cancer assessment.

Estimated cancer risk for the general U.S. population includes infants and children; therefore, a children's cancer risk estimate was not reported separately. For a description of the residential exposure scenarios considered in the aggregate assessment, see section 6.3. The aggregate cancer risk estimate for pyraflufen-ethyl is 1.1×10^{-6}. The Agency generally considers risks up to 3×10^{-6} to be within the negligible risk range and below the Agency's LOC. Therefore, the aggregate cancer risk estimate from pyraflufen-ethyl residues in food and drinking water is not of concern to EPA for the general U.S. population. This is a conservative estimate of pyraflufen-ethyl exposure based on the inputs to the dietary and residential exposure assessments.

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 pyraflufen-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available. Gas chromatography/mass spectroscopy (GC/MS) analytical methods determine Metabolite E-1 as its methyl ester (E-15) and monitor two ion transitions each for pyraflufen-ethyl and the E-15 analyte. The methods also contain appendices that provide parameters for other detection schemes such as GC/electron-capture detection (ECD), GC/nitrogen-phosphorus detection (NPD), and GC/MS/MS.

The methods 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 any MRLs for pyraflufen-ethyl.

V. Conclusion

Therefore, tolerances are established for residues of pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-difluoromethoxy)-1-methyl-1H-pyrazol-3-yl]-4-fluorophenoxy] acetate, including its metabolites and degradates. Compliance with these tolerances is to be determined by measuring only the sum of the parent pyraflufen-ethyl, and its acid metabolite, E-1,2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, calculated as the stoichiometric equivalent of pyraflufen-ethyl in or on commodities: Cottonseed subgroup 20C at 0.04 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.01 ppm; Fruit, stone, group 12-12 at 0.01 ppm; Hop, dried cones at 0.02 ppm; Nut, tree, group 14-12 at 0.01 ppm; Tropical and subtropical, small fruit, edible peel, subgroup 23A at 0.01 ppm and Vegetable, tuberous and corm, subgroup 1C at 0.02 ppm. In addition, existing tolerances on Cotton, undelinted seed; Fruit, stone, group 12; Grape; Nut, tree, group 14; Olive; Pistachio; and Potato are removed as they are superseded by this regulation.

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 tolerances 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 30, 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 § 180.585, amend the table in paragraph (a) as follows:

i. Add alphabetically the entries "Cottonseed subgroup 20C"; "Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F"; "Fruit, stone, group 12-12"; "Hop, dried cones"; "Nut, tree, group 14-12"; "Tropical and subtropical, small fruit, edible peel, subgroup 23A"; and "Vegetable, tuberous and corm, subgroup 1C".

ii. Remove the entries for "Cotton, undelinted seed"; "Fruit, stone, group 12"; "Grape"; "Nut, tree, group 14"; "Olive"; "Pistachio"; and "Potato".

The additions and revisions read as follows:

§ 180.585 Pyraflufen-ethyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Cottonseed subgroup 20C	0.04
* * * * * * *	
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	0.01
* * * * * * *	
Fruit, stone, group 12-12	0.01
* * * * * * *	
Hop, dried cones	0.02
* * * * * * *	
Nut, tree, group 14-12	0.01
* * * * * * *	
Tropical and subtropical, small fruit, edible peel, subgroup 23A	0.01
Vegetable, tuberous and corm, subgroup 1C	0.02
* * * * * * *	

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