in the Notification of Compliance Status under 40 CFR part 63, subpart WW and subpart SS, as referred to in § 63.1404 for storage vessels; under 40 CFR part 63, subpart SS, as referred to in § 63.1405 for continuous process vents; under § 63.1416(f)(1) through (3), (f)(5)(i) and (ii), and (f)(6)(i) and (ii) for continuous process vents; under § 63.1416(d)(1) for batch process vents; and under § 63.1416(e)(1) for aggregate batch vent streams. In addition, each owner or operator shall comply with paragraphs (e)(1)(i) and (ii) of this section.

* * * * *

(9) Data or other information used to demonstrate that an owner or operator may use engineering assessment to estimate emissions for a batch emission episode, as specified in § 63.1414(d)(6)(iii)(A).

* * * * *

(f) *Periodic Reports.* Except as specified in paragraph (f)(12) of this section, a report containing the information in paragraph (f)(2) of this section or containing the information in paragraphs (f)(3) through (11) and (13) through (16) of this section, as appropriate, shall be submitted semiannually no later than 60 days after the end of each 180 day period. In addition, for equipment leaks subject to § 63.1410, the owner or operator shall submit the information specified in 40 CFR part 63, subpart UU, and for heat exchange systems subject to § 63.1409, the owner or operator shall submit the information specified in § 63.1409. Section 63.1415 shall govern the use of monitoring data to determine compliance for emissions points required to apply controls by the provisions of this subpart.

(1) Except as specified in paragraph (f)(12) of this section, a report containing the information in paragraph (f)(2) of this section or containing the information in paragraphs (f)(3) through (11) and (13) through (16) of this section, as appropriate, shall be submitted semiannually no later than 60 days after the end of each 180 day period. The first report shall be submitted no later than 240 days after the date the Notification of Compliance Status is due and shall cover the 6-month period beginning on the date the Notification of Compliance Status is due. Subsequent reports shall cover each preceding 6-month period.

(2) If none of the compliance exceptions specified in paragraphs (f)(3) through (11) and (13) through (16) of this section occurred during the 6-month period, the Periodic Report required by paragraph (f)(1) of this section shall be a statement that the affected source was in compliance for the preceding 6-month period and no activities specified in paragraphs (f)(3) through (11) and (13) through (16) of this section occurred during the preceding 6-month period.

* * * * *

(5) If there is a deviation from the mass emission limit specified in § 63.1406(a)(1)(iii) or (a)(2)(iii), § 63.1407(b)(2), or § 63.1408(b)(2), the following information, as appropriate, shall be included:

* * * * *

(12) * * *

(ii) The quarterly reports shall include all information specified in paragraphs (f)(3) through (11) and (13) through (16) of this section applicable to the emission point for which quarterly reporting is required under paragraph (f)(12)(i) of this section. Information applicable to other emission points within the affected source shall be submitted in the semiannual reports required under paragraph (f)(1) of this section.

* * * * *

(14) If there is a deviation from the mass emission limit specified in § 63.1405(b)(2)(i), the report shall include the daily average emission rate calculated for each operating day for which a deviation occurred.

(15) If there is a deviation from the emission rate limit specified in § 63.1405(b)(2)(ii) or (iii), the report shall include the following information for each operating day for which a deviation occurred:

(i) The calculated average hourly emission rate.

(ii) The individual hourly emission rate data points making up the average hourly emission rate.

(16) For periods of storage vessel routine maintenance in which a control device is bypassed, the owner or operator shall submit the information specified in § 63.1416(g)(6)(i) through (iii) of this subpart.

(h) * * *

(7) Whenever a continuous process vent becomes subject to control requirements under § 63.1405, as a result of a process change, the owner or operator shall submit a report within 60 days after the performance test or applicability assessment, whichever is sooner. The report may be submitted as part of the next Periodic Report required by paragraph (f) of this section.

* * * * *

[FR Doc. 2018–22395 Filed 10–12–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0311; FRL–9980–56]

Pyraclostrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyraclostrobin in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 15, 2018. Objections and requests for hearings must be received on or before December 14, 2018, 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–2017–0311, 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–2017–0311 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 December 14, 2018. 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–2017–0311, 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 23, 2017 (82 FR 49020) (FRL–9967–37), 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 7E8569) by IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy] methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite, methyl-*N*-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl] phenylcarbamate expressed as parent compound in or on *Brassica,* leafy greens, subgroup 4–16B at 16.0 ppm, celtuce at 29.0 ppm, Florence, fennel at 29.0 ppm, kohlrabi at 5.0 ppm, leaf petiole vegetable subgroup 22B at 29.0 ppm, leafy greens subgroup 4–16A at 40 ppm, tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B at 0.6 ppm, and vegetable, *Brassica,* head and stem, group 5–16 at 5.0 ppm. The petition also requested that the following established tolerances be removed: Avocado at 0.6 ppm, banana at 0.04 ppm, *Brassica,* head and stem, subgroup 5A at 5.0 ppm, *Brassica* leafy greens, subgroup 5B, at 16.0 ppm, and vegetable, leafy, except *Brassica,* group 4 at 29 ppm. That document referenced a summary of the petition prepared by BASF, 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 pyraclostrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyraclostrobin 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.

The most consistently observed effects of pyraclostrobin exposure across species, genders, and treatment durations were diarrhea, decreased body weight, and decreased food consumption. Pyraclostrobin also causes intestinal disturbance as indicated by increased incidence of diarrhea or duodenum mucosal thickening. These intestinal effects appeared to be related to the irritating action on the mucus membranes as demonstrated by redness and chemosis (*i.e.,* swelling of the conjunctiva) seen in the primary eye irritation study. In the rat acute and subchronic neurotoxicity studies, neuropathology and behavior changes were not observed.

In the rat and rabbit developmental toxicity studies, developmental toxicity (*i.e.* skeletal variations, post-implantation loss, and fetal resorption) was observed, as well as maternal toxicity (*i.e.* diarrhea, decreased body weight, food consumption, and clinical signs of toxicity). In the reproduction study, systemic toxicity manifested as decreased body weight in both the parents and offspring; no reproductive toxicity was observed.

In the rat subchronic inhalation toxicity studies, inhalation toxicity

consisted of both portal of entry effects (*i.e.,* olfactory atrophy/necrosis and histiocytosis in the lungs) and systemic effects (*i.e.,* hyperplasia in the duodenum).

Pyraclostrobin was classified by the Agency as ''Not Likely to be Carcinogenic to Humans'' based on the lack of treatment-related increase in tumor incidence in adequately conducted carcinogenicity studies in rats and mice. Pyraclostrobin did not cause mutagenicity or genotoxicity in the in vivo and in vitro assays. Pyraclostrobin did not cause immunotoxicity in mice assays.

Specific information on the studies received and the nature of the adverse effects caused by pyraclostrobin 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* on pages 34–39 in the document titled ''*Pyraclostrobin. Human Health Risk Assessment for a Petition for the Establishment of Use on Greenhouse-Grown Leafy Greens, Except Head Lettuce, Subgroup 4–16A; Cucurbit Vegetables, Group 9; and Fruiting Vegetables, Group 8–10 and Crop Group Conversions and Expansion of Tolerances for Brassica, Leafy Greens, Subgroup 4–16B; Celtuce; Florence Fennel; Kohlrabi; Leaf Petiole Vegetables, Subgroup 22B; Tropical and Subtropical, Medium to Large Fruit, Inedible Peel, Subgroup 23B; and Brassica Head and Stem, Group 5–16 and a Revised Tolerance Level for Leafy Greens, Subgroup 4–16A*'' in docket ID number EPA–HQ–OPP–2017–0311.

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 pyraclostrobin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 10, 2015 (80 FR 19231) (FRL–9925–02).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyraclostrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing pyraclostrobin tolerances in 40 CFR 180.582. EPA assessed dietary exposures from pyraclostrobin 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 pyraclostrobin. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the acute dietary exposure assessments were performed assuming 100 percent crop treated (PCT) and incorporating tolerance-level or highest field-trial 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, the chronic dietary exposure assessments were performed using average percent crop treated estimates and tolerance-level or average field-trial residues.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that pyraclostrobin 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, 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 estimated the PCT for existing uses in the chronic dietary assessment as follows:

Almonds 45%; apples 20%; apricots 30%; barley 10%; green beans 5%; blueberries 40%; broccoli 5%; Brussels sprouts 15%; cabbage 10%; caneberries 50%; cantaloupes 15%; carrots 35%; cauliflower 5%; celery <2.5%; cherries 55%; chicory 5%; corn 10%; cotton (seed treatment) 10%; cucumber 5%; dry beans/peas 10%; garlic 10%; grapefruit 35%; grapes 30%; hazelnuts 20%; lemons 5%; lettuce 5%; nectarines 15%; oats 5%; onions 30%; oranges 5%; peaches 25%; peanuts 20%; pears 20%; green peas 5%; pecans 5%; peppers 15%; pistachios 30%; potatoes 20%; pumpkins 15%; soybeans (seed treatment) 10%; spinach 5%; squash 15%; strawberries 65%; sugar beets 50%; sugarcane 5%; sweet corn 5%; tangerines 10%; tomatoes 25%; walnuts 10%; watermelons 25%; wheat 5%.

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 2.5%, in which case 2.5% is used as the average PCT, or less than 1%, in which case 1% is used as the average PCT.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for pyraclostrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyraclostrobin. 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 Root Zone Model and Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of pyraclostrobin for acute exposures are estimated to be 35.6 parts per billion (ppb) for surface water and 0.02 ppb for ground water and for chronic exposures are estimated to be 2.3 ppb for surface water and 0.02 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 35.6 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 2.3 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).

Pyraclostrobin is currently registered for the following uses that could result in residential handler and post-application exposures: Treated gardens, fruit or nut trees, tomato transplants, and turf. EPA assessed residential exposure using the following assumptions: Short-term adult handler exposures via the dermal and inhalation routes resulting from application of pyraclostrobin to gardens, trees, and turf. Short-term dermal post-application exposures were assessed for adults, youth 11 to 16 years old, and children 6 to 11 years old. Short-term dermal and incidental oral exposures were assessed for children 1 to less than 2 years old. Intermediate-term exposures are not likely because of the intermittent nature of applications in residential settings.

For the aggregate assessment, inhalation and dermal exposures were not aggregated together because the toxicity effect from the inhalation route of exposure was different than the effect from the dermal route of exposure. The scenarios with the highest residential exposures that were used in the short-term aggregate assessment for pyraclostrobin are as follows:

- Adult short-term aggregate assessment—residential dermal post-application exposure via activities on treated turf.
- Youth (11 to 16 years old) short-term aggregate assessment—residential dermal exposure from post-application golfing on treated turf.
- Children (6 to 11 years old) short-term aggregate assessment—residential dermal exposures from post-application activities in treated gardens.
- Children (1 to less than 2 years old) short-term aggregate assessment—residential dermal and hand-to-mouth exposures from post-application exposure to treated turf.

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 pyraclostrobin to share a common mechanism of toxicity with any other substances, and pyraclostrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyraclostrobin 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.* There is no evidence that pyraclostrobin results in increased quantitative susceptibility in rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. Although there is evidence of increased qualitative susceptibility in the prenatal development study in rabbits, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of pyraclostrobin. The degree of concern for prenatal and/or postnatal toxicity is low.

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 pyraclostrobin is complete.

ii. There is no indication that pyraclostrobin is a neurotoxic chemical. Effects seen in the acute and subchronic neurotoxicity studies in rats are considered to reflect perturbations in mitochondrial respiration leading to effects on energy production rather than signs of neurotoxicity; therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that pyraclostrobin results in increased quantitative susceptibility in rats in the prenatal developmental study or in young rats in the 2-generation reproduction study. The prenatal rabbit developmental toxicity study showed

evidence of increased qualitative susceptibility to prenatal rabbits; however, this study was chosen for endpoint selection for the acute dietary (females 13–49) and short-term dermal exposure scenarios. This study has a clearly defined NOAEL of 5.0 mg/kg/day. EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of pyraclostrobin. The degree of concern for prenatal and/or postnatal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary exposure assessments were performed assuming 100 PCT and tolerance-level or highest field trial residues. The chronic dietary exposure assessments were performed using average PCT estimates, when available, and tolerance-level or average field trial residues. These data are reliable and are not expected to underestimate risks to adults or children. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyraclostrobin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pyraclostrobin.

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 pyraclostrobin will occupy 88% of the aPAD for females 13–49 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyraclostrobin from food and water will utilize 29% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pyraclostrobin 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).

Pyraclostrobin 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 pyraclostrobin.

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 110 for children 1 to 2 years old, 360 for children 6 to 11 years old, 1500 for youth 11 to 16 years old, and 230 for adults. Because EPA's level of concern for pyraclostrobin is a MOE of 100 or below, these MOEs are not of concern.

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

Intermediate-term adverse effects were identified; however, pyraclostrobin 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 pyraclostrobin.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Two adequate methods are available to enforce the tolerance expression for residues of pyraclostrobin and the metabolite BF 500–3 in or on plant commodities: A liquid chromatography with tandem mass spectrometry (LC/MS/MS) method, BASF Method D9908; and a high-performance LC with ultraviolet detection (HPLC/UV) method, Method D9904. The methods may be found in the Pesticide Analytical Manual, Volume I.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for pyraclostrobin in or on various commodities including kale, collards, curly kale, Scotch kale, thousand-headed kale (not including marrow stem kale) at 1 ppm; radish leaves (including radish tops) at 20 ppm; lettuce, head at 2 ppm; banana at 0.02 ppm; mango at 0.05 ppm; papaya at 0.15 ppm; Brussels sprouts at 0.3 ppm; cabbages, head at 0.2 ppm; and flower-head brassicas (includes broccoli, broccoli Chinese and cauliflower) at 0.1 ppm. These MRLs are different than the tolerances established for pyraclostrobin in the United States, however, they cannot be harmonized because the tolerance/MRL expressions for the U.S. and Codex are not harmonized and the submitted residue data support higher tolerance levels than those set by Codex, indicating that harmonization would cause legal application of pyraclostrobin by U.S. users to result in exceedances of domestic tolerances.

C. Revisions to Petitioned-for Tolerances

For tolerance values that vary from what the petitioner requested, EPA is

establishing tolerance values in order to conform to current Agency policy on significant figures. The tolerance for tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B is not being established at this time. The request for a tolerance for subgroup 24B was submitted in connection with an application for registration of a pesticide product with multiple active ingredients. Because one of those active ingredients is not currently approved for use on the commodities in subgroup 24B, EPA is not approving use of the combination product on commodities in subgroup 24B. Therefore, EPA is not establishing the tolerance for subgroup 24B because it is not necessary at this time. Because a tolerance is not being established for subgroup 24B, the existing tolerances for avocado and banana are not being removed as proposed.

V. Conclusion

Therefore, tolerances are established for residues of pyraclostrobin carbamic acid, [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy] methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite, methyl-*N*-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl] phenylcarbamate (BF 500–3), expressed as parent compound, in or on *Brassica,* leafy greens, subgroup 4–16B, except watercress at 16 ppm; celtuce at 29 ppm; fennel, Florence at 29 ppm; kohlrabi at 5.0 ppm; leaf petiole vegetable, subgroup 22B at 29 ppm; leafy greens, subgroup 4–16A at 40 ppm; and vegetable, *Brassica,* head and stem, group 5–16 at 5.0 ppm. Additionally, the following established tolerances are removed as unnecessary due to the establishment of the above tolerances: *Brassica,* head and stem, subgroup 5A; *Brassica* leafy greens, subgroup 5B; and vegetable, leafy, except brassica, group 4.

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 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: October 2, 2018.

Michael L. 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 § 180.582:

■ i. Add alphabetically the commodities ''*Brassica,* leafy greens, subgroup 4–16B, except watercress''; ''celtuce''; ''fennel, Florence''; ''kohlrabi''; ''leaf petiole vegetable, subgroup 22B''; ''leafy greens, subgroup 4–16A''; and ''vegetable, *Brassica,* head and stem, group 5–16'' to the table in paragraph (a)(1); and

■ ii. Remove the entries for ''*Brassica,* head and stem, subgroup 5A''; ''*Brassica,* leafy greens, subgroup 5B''; and ''vegetable, leafy, except brassica, group 4'' from the table in paragraph (a)(1).

The additions read as follows:

§ 180.582 Pyraclostrobin; tolerances for residues.

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

Commodity	Parts per million
* * * * *	
Brassica, leafy greens, subgroup 4–16B, except watercress	16
* * * * *	
Celtuce	29
* * * * *	
Fennel, Florence	29
* * * * *	
Kohlrabi	5.0
Leaf petiole vegetable, subgroup 22B	29
Leafy greens, subgroup 4–16A	40
* * * * *	
Vegetable, *Brassica,* head and stem, group 5–16	5.0

Commodity	Parts per million
* * * * *	

* * * * *

[FR Doc. 2018–22282 Filed 10–12–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0273; FRL–9983–96]

Etoxazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of etoxazole in or on multiple commodities which are identified and discussed later in this document. In addition, it removes certain previously established tolerances that are superseded by this final rule. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 15, 2018. Objections and requests for hearings must be received on or before December 14, 2018, 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–2017–0273, 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 L. 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–2017–0273 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 December 14, 2018. 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–2017–0273, 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 23, 2017 (82 FR 49020) (FRL–9967–37), 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 7E8559) by IR–4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, New Jersey 08540. The petition requested that 40 CFR 180.593 be amended by establishing tolerances for residues of the miticide/insecticide etoxazole, (2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole), in or on Corn, sweet, kernel plus cob with husks removed at 0.01 parts per million (ppm); Corn, sweet, forage at 1.5 ppm; Corn, sweet, stover at 5.0 ppm; Fruit, pome, group 11–10 at 0.20 ppm; Nut, tree, group 14–12 at 0.01 ppm; Fruit, stone, group 12–12 at 1.0 ppm; and Cottonseed subgroup 20C at 0.05 ppm. In addition, upon establishment of new tolerances referenced above, the petitioner requested the removal of existing tolerances in 40 CFR 180.593 for residues of etoxazole in or on Fruit, pome, group 11 at 0.20 ppm; Fruit, stone, group 12, except plum at 1.0 ppm; Nut, tree, group 14 at 0.01 ppm; Cotton, undelinted seed at 0.05 ppm; Pistachio at 0.01 ppm; Plum at 0.15 ppm; and Plum, prune, dried at 0.30 ppm. That document referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Consistent with the authority in FFDCA 408(d)(4)(A)(i), EPA is issuing tolerances that vary from what the