



This document is scheduled to be published in the Federal Register on 04/10/2015 and available online at <http://federalregister.gov/a/2015-08079>, and on FDsys.gov

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0798; FRL-9925-02]

Pyraclostrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyraclostrobin in or on the herb subgroup 19A, dill seed, the stone fruit group 12-12, and the tree nut group 14-12, except pistachio. 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-2013-0798, 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: Susan Lewis, 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 FFDC 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-2013-0798 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-2013-0798, 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 25, 2014 (79 FR 10458) (FRL-9906-77), 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 3E8216) by IR-4, 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)-1H-pyrazol-3-yl]oxy]methyl]phenylcarbamate) (BF 500-3), expressed as parent compound, in or on herb, subgroup 19A at 85 ppm; and dill, seed at 100 ppm and by changing the existing entries for “fruit, stone, group 12” at 2.5 ppm to “fruit, stone, group 12-12” at 2.5 ppm; and “nut, tree, group 14” at 0.04 ppm to “nut, tree, group 14-12, except pistachio” at 0.04 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.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established for some commodities. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

occupational exposure. Section 408(b)(2)(C) of FFDCFA 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 FFDCFA section 408(b)(2)(D), and the factors specified in FFDCFA 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.

There are no concerns for reproductive susceptibility, neurotoxicity, mutagenicity, genotoxicity, or immunotoxicity. The most consistently observed effects resulting from pyraclostrobin exposure across species, genders, and treatment durations were diarrhea and decreased body weight, body weight gain, and food consumption. Pyraclostrobin also causes intestinal disturbances, 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 irritation 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 developmental toxicity study, developmental toxicity including an increased incidence of dilated renal pelvis and cervical ribs occurred at a dose greater than the dose causing maternal toxicity (including decreased body weights and body weight gains and reduced food consumption and reduced food efficiency). The rabbit developmental toxicity study indicates qualitative evidence of increased developmental susceptibility based on increased resorptions per litter, increased post-implantation loss and dams with total resorptions, in the presence of maternal toxicity (reduced body weight gain, food consumption, and food efficiency). In a dose range-finding 1-generation reproduction study, systemic toxicity was manifested as decreased body weight and body weight gain in both the parents and offspring. The effects occurred at the same dose levels for both parental and the offspring, but the decrease in pup weight was more than that in the parental animals. However, the body weight effect was not found in the guideline 2-generation reproduction study in either parental or offspring animals at similar dose level. No reproductive toxicity was seen.

Pyraclostrobin has been classified as not likely to be carcinogenic to humans based on the lack of treated 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, nor did it cause immunotoxicity in T-cell dependent antibody response assays in mice with preliminary review.

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> in document "Pyraclostrobin – Human Health Risk Assessment for a Section 3 Registration of New Uses on Herb Subgroup 19A and Dill Seed, Plus Crop Group

Conversions on Stone Fruit Group 12-12 and Tree Nut Group 14-12” at page 29 in docket ID number EPA-HQ-OPP-2013-0798.

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

Table 1.--Summary of Toxicological Doses and Endpoints for Pyraclostrobin 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
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Acute dietary (Females 13-50 years of age)	NOAEL = 5.0 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.05 mg/kg/day aPAD = 0.05 mg/kg/day	<u>Developmental Toxicity – Rabbit</u> LOAEL = 10.0 mg/kg/day based on developmental toxicity findings of increased resorptions.
Acute dietary (General population including infants and children)	NOAEL = 300 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 3.0 mg/kg/day aPAD = 3.0 mg/kg/day	<u>Acute Neurotoxicity – Rat</u> LOAEL = 1,000 mg/kg/day based on decreased body weight gain in males.
Chronic dietary (All populations)	NOAEL= 3.4 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.034 mg/kg/day cPAD = 0.034 mg/kg/day	<u>Carcinogenicity – Rat</u> LOAEL = 9.2 mg/kg/day based on decreased body weight, kidney tubular casts and atrophy in both sexes; increased incidence of liver necrosis and erosion/ulceration of the glandular- stomach and fore- stomach in males.
Incidental oral short- term (1 to 30 days) and intermediate- term (1 to 6 months)	NOAEL= 5.8 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	<u>Subchronic Toxicity – Dog</u> LOAEL = 12.9 mg/kg/day based on increased incidence of diarrhea, clinical chemistry changes, duodenum mucosal hypertrophy, and decreased body weight and food efficiency.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Oral study NOAEL = 5.0 mg/kg/day (dermal absorption rate = 14%) UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	<u>Developmental Toxicity – Rabbit</u> LOAEL = 10.0 mg/kg/day based on developmental toxicity findings of increased resorptions and maternal toxicity based on decreased food efficiency.
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Inhalation study NOAEL= 0.010 mg/kg/day UF _A = 3x	LOC for MOE = 30	<u>Inhalation Toxicity – Rat</u> LOAEL = 6.9 mg/kg/day (air concentration = 0.03 mg/L) based on duodenum mucosal

	$UF_H = 10x$ $FQPA\ SF = 1x$ $f_{\text{Handler}} =$ $16.7\ \text{L/min}$ $HEC_{\text{Handler}} =$ $0.00131\ \text{mg/L}$ $HEC_{\text{Bystander}} =$ $0.00023\ \text{mg/L}$ $HED_{\text{Handler}} =$ $0.038\ \text{mg/kg/day}$		hyperplasia and respiratory system findings including alveolar histiocytosis and olfactory atrophy/necrosis in nasal tissue.
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_H = potential variation in sensitivity among members of the human population (intraspecies). HEC = Human Equivalent Concentration. HED = Human Equivalent Dose. f = Respiratory frequency

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 Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16, which uses food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) from 2003 through 2008. As to residue levels in food, EPA used tolerance-level residues or highest field trial residues, 100 percent crop treated (PCT), and empirical or default processing factors. Experimentally-derived processing factors were used for fruit juices, tomato, sugarcane, and wheat commodities. For all other processed commodities, DEEM default processing factors were assumed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA included tolerance-level or average field trial residues, average PCT estimates when available, and empirical processing factors. Experimentally-derived processing factors were used for fruit juices, tomato, sugar cane, and wheat commodities. For all other processed commodities, DEEM default processing factors were assumed.

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, the exposure estimate does not understate exposure for the population in such area.

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

The Agency estimated the PCT for existing uses as follows:

Almonds 40%; apples 15%; apricots 25%; barley 10%; green beans <2.5%; blueberries 45%; broccoli 5%; cabbage 10%; caneberries 50%; cantaloupes 15%; carrots 35%; cauliflower <2.5%; celery <2.5%; cherries 50%; corn 10%; cotton <2.5%; cotton (seed treatment) 10%; cucumber 10%; dry beans/peas 10%; garlic 10%; grapefruit 30%; grapes 30%; hazelnuts (filberts) 20%; lemons <2.5%; lettuce 5%; nectarines 10%; onions 25%; oranges 5%; peaches 20%; peanuts 25%; pears 15%; green peas 5%; pecans <2.5%; peppers 10%; pistachios 30%; plums/prunes 5%; potatoes 20%; pumpkins 20%; rice <1%; soybeans 5%; soybeans (seed treatment) 5%; spinach 5%; squash 15%; strawberries 65%; sugar beets 45%; sweet corn 5%;

tangelos 15%; tangerines 10%; tomatoes 25%; walnuts <1%; watermelons 30%; wheat 5%; wheat (seed treatment) <1%.

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%.

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 pyraclostrobin 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 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://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model for Groundwater (PRZM-GW) models, 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. Chronic exposures for non-cancer assessments 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 acute dietary risk assessment, the water concentration value of 35.6 ppb was used to assess the contribution to drinking water. For 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 <2 years old. Based on the registered uses of pyraclostrobin on residential and golf course turf, intermediate-term post-application exposures are possible. However, since the short- and intermediate-term endpoints and PODs for dermal and oral routes are the same, the short-term exposure and risk estimates are considered to be protective of potential intermediate-term exposure and risk.

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 (11-16 years old) short-term aggregate assessment - residential dermal exposure from post-application golfing on treated turf.
- Children (6-11 years old) short-term aggregate assessment - residential dermal exposures from post-application activities in treated gardens.
- Children (1<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://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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://www.epa.gov/pesticides/cumulative>.

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 that pyraclostrobin results in increased susceptibility in rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. Although there is qualitative evidence of increased

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 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 qualitative evidence of increased 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 highest 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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyraclostrobin will occupy 87% 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 27% 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 1-2 years old, 380 for children 6-11 years old, 1,600 for youth 11-16 years old, and 230 for adults from post-application exposures. 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). Pyraclostrobin is currently registered for uses that could result in intermediate-term residential exposure; however, since the short- and intermediate-term endpoints and PODs for dermal and oral routes are the same, the short-term exposure and risk estimates are considered to be protective of potential intermediate-term exposure and risk and an intermediate-term aggregate assessment was not performed.

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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex and U.S. residue definitions for pyraclostrobin residues on plant commodities are different. The Codex definition is pyraclostrobin, whereas the U.S. definition is pyraclostrobin and its desmethoxy metabolite. Codex has not established MRLs for pyraclostrobin on herbs or dill seed, and therefore there are no harmonization issues for those commodities. Codex has established MRLs for some members of the stone fruit group, i.e., cherries (3 mg/kg), peach/nectarine (0.3 mg/kg), and plums (0.8 ppm), but does not have a

group tolerance. EPA has decided to issue a single group tolerance as requested for the stone fruit crop group, rather than harmonize with the individual MRLs for cherry, peach/nectarine, and plum, because adequate data supports the crop group tolerance. Codex has established a tree nut group tolerance at 0.02 mg/kg. The U.S. tolerance cannot be lowered, as it includes parent and a metabolite, each at 0.02 ppm, or 0.04 ppm total.

C. Revisions to Petitioned-For Tolerances

The tolerances being established for the herb subgroup 19A (40 ppm) and dill seed (40 ppm) are different than what the petitioner requested (85 ppm and 100 ppm, respectively). The requested tolerance levels for the herb subgroup 19A and dill seed were based on the use of field trial data without adjustment for the exaggerated application rate (2.7X) represented by those trials. Each of the two applications of pyraclostrobin were conducted at 2.7X the label rate, and the total seasonal rate was 2.7X the label rate. Using the assumption of proportionality, i.e., that the residue levels are proportional to the rate of application, the residue results may be adjusted to the concentrations expected at the 1X rate. The tolerance estimates at the 1X rate are 40 ppm for herb subgroup 19A and 40 ppm for dill seed.

V. Conclusion

Therefore, tolerances are established for residues of 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)-1H-pyrazol-3-yl]oxy]methyl]phenylcarbamate) (BF 500-3), expressed as parent compound, in or on herb, subgroup 19A at 40 ppm; and dill, seed at 40 ppm. Additionally, the existing entries for “fruit, stone, group 12” at 2.5 ppm is modified to read “fruit, stone, group 12-12” at 2.5 ppm; and “nut, tree, group 14” at 0.04 ppm is modified to read “nut, tree, group 14-12, except pistachio” at 0.04 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCa section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus,

the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 1, 2015.

Susan Lewis,
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:

a. Add alphabetically the entries for “Dill, seed”, “Fruit, stone, group 12-12”, “Herb subgroup 19A”, and “Nut, tree, group 14-12, except pistachio” to the table in paragraph (a)(1).

b. Remove the entries for “Fruit, stone, group 12”, and “Nut, tree, group 14” in the table in paragraph (a)(1).

The amendments read as follows:

§ 180.582 Pyraclostrobin; tolerances for residues.

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

Commodity	Parts per million
* * *	* * *
Dill, seed	40
* * *	* * *
Fruit, stone, group 12-12	2.5
* * *	* * *
Herb subgroup 19A	40
* * *	* * *
Nut, tree, group 14-12, except pistachio	0.04
* * *	* * *

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