



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2017-0310; FRL-9979-17]**

**Boscalid; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of boscalid 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 [*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-2017-0310, 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](mailto: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](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-2017-0310 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-2017-0310, 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 FFDC section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8564) 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 180.589 be amended by establishing tolerances for residues of the fungicide boscalid, 3-pyridinecarboxamide, 2-chloro-*N*-(4'-chloro[1,1'-biphenyl]-2-yl) in or on *Brassica* leafy greens subgroup 4-16B at 50 parts per million; celtuce at 45 ppm; Florence, fennel at 45 ppm; kohlrabi at 6 ppm; leaf petiole vegetable subgroup 22B at 45 ppm; leafy greens subgroup 4-16A at 70 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 2.5 ppm; pea and bean, succulent shelled, subgroup 6B at 0.6 ppm; vegetable, *Brassica* head and stem group 5-16 at 6 ppm; vegetable, cucurbit group 9 at 3 ppm; and vegetable root, except sugar beet, subgroup 1B at 2.0 ppm. The petition also requested the removal of the established tolerances of boscalid in or on *Brassica*, head and stem, subgroup 5A at 3.0 ppm, *Brassica*, leafy greens, subgroup 5B at 18 ppm, cucumber at 0.5 ppm, leaf petioles subgroup 4B at 45 ppm; leafy greens subgroup 4A, except head lettuce and leaf lettuce at 60 ppm, lettuce, head at 6.5 ppm, lettuce, leaf at 11 ppm, pea and bean, dried shelled, except soybean, subgroup 6C, except cowpea, field pea and grain lupin at 2.5 ppm; pea and bean, succulent shelled, subgroup 6B, except cowpea at 0.6 ppm; turnip, greens at 40 ppm, vegetable, cucurbit group 9, except cucumber at 1.6 ppm, and vegetable, root, subgroup 1A, except sugar beet, garden beet, radish and turnip at 1.0 ppm and the removal of the established tolerances for indirect or inadvertent residues of boscalid, in or on beet, garden, roots at 0.1 ppm; cowpea, seed at 0.1 ppm; lupin, grain, grain at 0.1 ppm; pea, field, seed at 0.1 ppm; radish, roots at 0.1 ppm; and turnip, roots at 0.1 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 some of the tolerances are being established. The reasons for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCCA 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 FFDCCA 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 FFDCCA 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 FFDCCA section 408(b)(2)(D), and the factors specified in FFDCCA 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 boscalid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with boscalid follows.

#### *A. Toxicological Profile*

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

In mammals, the target organs are the liver and the thyroid (indirectly from liver adaptive response). In subchronic and chronic feeding studies in rats, mice and dogs, boscalid generally caused decreased body weights (primarily in mice) and effects on the liver (increase in weights, changes in enzyme levels and histopathological changes) as well as on the thyroid (increase in weights and histopathological changes). Mode of action studies conducted in rats indicated that boscalid has a direct effect upon the liver and that the thyroid effects are secondary. A reversibility study in rats indicated that both liver and thyroid parameters returned to control values after the animals were placed on control diet. Absolute and/or relative thyroid weights were elevated in rats and dogs, but there were no histopathological changes observed in the thyroid in either mice or dogs.

In a developmental toxicity study in rats, no developmental toxicity was observed in the fetuses at the highest dose tested (limit dose). No effects were noted in the dams in this study. In a developmental toxicity study in rabbits, an increased incidence of abortions or early delivery was observed at the limit dose. There was quantitative evidence of increased susceptibility in the two-generation reproduction study in rats, where decreases in body weights in male offspring were seen at a dose that was lower than the dose that induced parental/systemic toxicity. There was quantitative evidence of increased susceptibility in the developmental neurotoxicity study in rats, where decreases in pup body weights on post-natal day four (PND4) and body weight gains (PND 1-4) were seen in the absence of any maternal toxicity.

In a 2-year chronic toxicity study and a 2-year carcinogenicity study in male and female rats, the combined data showed an increased trend in thyroid follicular cell adenomas that appeared to be treatment-related in males. This was supported by thyroid hypertrophy and hyperplasia of follicular cells at the same dose as well as increased thyroid weights plus mechanistic data. Despite these findings, the Agency has determined that quantification of the cancer risk is not necessary because (1) the adenomas occurred at dose levels above the level used to establish the chronic population adjusted dose (cPAD); (2) statistically significant increases were only seen for benign tumors (adenomas) and not for malignant ones (carcinomas); (3) the increase in adenomas in females was slight; and (4) there was no evidence of mutagenicity. Furthermore, the mouse carcinogenicity study was negative.

There was no evidence of neurotoxicity in rats in the acute, subchronic or developmental studies up to the limit dose. No neurotoxic observations were noted in any of the other studies in any species. Similarly, there was no evidence of immunotoxicity in the available immunotoxicity study in rats, or in any of the other studies in the database.

Specific information on the studies received and the nature of the adverse effects caused by boscalid 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 35-40 of the document titled "*Boscalid. Human Health Risk Assessment of Tolerance Requests for Brassica, Leafy Greens, Subgroup 4-16B; Celtuce; Florence Fennel; Kohlrabi; Leaf Petiole Vegetable Subgroup 22B; Leafy Greens Subgroup 4-16A; Pea and Bean, Dried Shelled, Except Soybean, Subgroup 6C; Pea and Bean, Succulent Shelled, Subgroup 6B; Vegetable, Brassica, Head and Stem, Group 5-16, Vegetable, Cucurbit, Group 9; and Vegetable, Root, Except Sugar Beet, Subgroup 1B; and Associated Registration Requests on*

*Greenhouse-grown Fruiting Vegetables, Cucurbit Vegetables, and Leafy Vegetables*” in docket ID number EPA-HQ-OPP-2017-0310.

#### *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 boscalid used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of November 8, 2013 (78 FR 67042) (FRL-9401-5).

#### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to boscalid, EPA considered exposure under the petitioned-for tolerances as well as all existing boscalid tolerances in 40 CFR 180.589. EPA assessed dietary exposures from boscalid 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 boscalid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used food consumption information from the 2003-2008 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). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT).

iii. *Cancer.* EPA has concluded that the chronic endpoint will be protective of potential cancer effects. EPA's estimate of chronic exposure as described above is relied upon to evaluate whether any exposure could exceed the chronic population adjusted doses (cPAD) and thus pose a cancer risk.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for boscalid. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for boscalid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of boscalid. 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 /Exposure Analysis Modeling System (PRZM/EXAMS) model and Pesticide Root Zone Model Ground Water (PRZM GW) model, the estimated drinking water concentrations (EDWCs) of boscalid for chronic exposures are estimated to be 26.4 ppb for surface water and 697 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration of value 697 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).

Boscalid is currently registered for the following uses that could result in residential exposures: Golf course turf, residential fruit and nut trees, and residential ornamentals and landscape gardens. EPA assessed residential exposure using the following assumptions:

All residential exposures are considered short-term in duration. The residential handler assessment included short-term exposures via the dermal and inhalation routes from treating residential ornamentals, landscape gardens, and trees.

In terms of post-application exposure, there is the potential for dermal post-application exposure for individuals as a result of being in an environment that has been previously treated with boscalid. Short-term dermal exposures were assessed for adults, youth 11 to 16 years old, and children 6 to 11 years old. Incidental oral exposure to children 1 to 2 years old is not expected from treated turf because boscalid is registered for use only on golf course turf and residential gardens and trees, and the extent to which young children utilize these areas is low.

The scenarios used in the aggregate assessment were those that resulted in the highest exposures. The highest exposures for all age groups were associated with only residential post-application dermal exposures, not inhalation exposures, and consist of the following:

- The residential dermal exposure for use in the adult aggregate assessment reflects dermal exposure from post-application activities on treated gardens.
- The residential dermal exposure for use in the youth (11-16 years old) aggregate assessment reflects dermal exposure from post-application golfing on treated turf.
- The residential dermal exposure for use in the child (6-11 years old) aggregate assessment reflects dermal exposure from post-application activities in treated gardens.

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 boscalid to share a common mechanism of toxicity with any other substances, and boscalid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that boscalid 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 was no evidence of increased susceptibility in the rat developmental study as no developmental toxicity was seen at the highest dose tested (limit dose).

There was evidence of increased qualitative susceptibility in the rabbit developmental study as characterized by an increased incidence of abortions or early delivery at the limit dose. It could not be ascertained if the abortions were the result of a treatment-related effect on the dams, the fetuses or both. It was concluded that the degree of concern is low because the increased abortions or early delivery was seen only at the limit dose and the abortions may have been due to maternal stress.

There was evidence of increased quantitative susceptibility seen in the rat 2-generation reproduction study and the developmental neurotoxicity study, in that reduced body weights were seen in the offspring at dose levels where no parental toxicity was observed. However, the degree of concern is low because the dose selected for chronic dietary and non-dietary

exposure risk assessments is lower than the dose that caused the body weight effects, and the effect was shown to be reversible in the developmental neurotoxicity study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x for all scenarios except for inhalation exposures where the 10X FQPA SF was retained. That decision is based on the following findings:

i. The toxicity database is complete, with the exception of a subchronic inhalation study. EPA is retaining a 10X FQPA SF for assessing residential inhalation risks to adult applicators.

ii. There is no indication that boscalid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. For the reasons listed in Unit III.D.2., the Agency has concluded that there are no residual uncertainties concerning the potential for prenatal and post-natal toxicity. iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to boscalid in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by boscalid.

#### *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, boscalid 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 boscalid from food and water will utilize 57% of the cPAD for children 1 to 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 boscalid 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).

Boscalid 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 boscalid.

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 300 for adults, 660 for youths 11 to 16 years old and 300 for children 6 to 11 years old. Because EPA's level of concern for boscalid 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).

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

5. *Aggregate cancer risk for U.S. population.* Based on the data summarized in Unit III.A., EPA has concluded that the cPAD is protective of possible cancer effects. Given the results of the chronic risk assessment, cancer risk resulting from exposure to boscalid is not of concern.

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 boscalid residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (gas chromatography/mass spectrometry (GC/MS)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: [residuemethods@epa.gov](mailto: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 established MRLs for boscalid in or on several of the commodities that are different than the tolerances established for boscalid in the United States, however, the tolerance expression in the U.S. differs from the Codex MRL expression. Also, 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. Therefore, further harmonization of U.S. tolerances with Codex MRLs is not possible at this time.

### *C. Revisions to Petitioned-For Tolerances*

The petitioner proposed a tolerance of 50 ppm for the *Brassica*, leafy greens, subgroup 4-16B, but the Agency is establishing the tolerance at 60 ppm, based on the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures. The Agency has also modified some of the tolerances to be consistent with EPA's policy on significant figures.

## **V. Conclusion**

Therefore, tolerances are established for residues of boscalid in or on *Brassica*, leafy greens subgroup 4-16B, except watercress at 60 ppm; celtuce at 45 ppm; Florence fennel at 45 ppm; kohlrabi at 6.0 ppm; leaf petiole vegetable subgroup 22B at 45 ppm; leafy greens subgroup 4-16A at 70 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 2.5 ppm; pea and bean, succulent shelled, subgroup 6B at 0.60 ppm; vegetable, *Brassica*, head and stem, group 5-16 at 6.0 ppm; vegetable, cucurbit, group 9 at 3.0 ppm; and vegetable, root, except sugar beet, subgroup 1B at 2.0 ppm.

Additionally, the following existing tolerances and inadvertent tolerances are removed as unnecessary due to the establishment of the new tolerances. *Tolerances*: *Brassica*, head and stem, subgroup 5A; *Brassica*, leafy greens, subgroup 5B; cucumber; leaf petioles, subgroup 4B; leafy greens, subgroup 4A, except head lettuce and leaf lettuce; lettuce, head; lettuce, leaf; pea and bean, dried shelled, except soybean, subgroup 6C, except cowpea, field pea, and grain lupin; pea and bean, succulent shelled, subgroup 6B, except cowpea; turnip, greens; vegetable, cucurbit, group 9, except cucumber; vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip. *Inadvertent tolerances*: beet, garden, roots; cowpea, seed; lupin, grain, grain; pea field, seed; radish, roots; turnip, roots.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCFA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use"

(66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low -Income Populations” (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCa section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

#### **VII. Congressional Review Act**

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

#### **List of Subjects in 40 CFR Part 180**

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

Dated: October 4, 2018.

Michael Goodis,  
*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40CFR 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 § 180.589:

a. In the table to paragraph (a):

i. Add in alphanumeric order entries for “*Brassica*, leafy greens, subgroup 4-16B, except watercress”; “Celtuce”; “Fennel, Florence”; “Kohlrabi”; “Leaf petiole vegetable subgroup 22B”; “Leafy greens subgroup 4-16A”; “Pea and bean, dried shelled, except soybean, subgroup 6C”; “Pea and bean, succulent shelled, subgroup 6B”; “Vegetable, *Brassica*, head and stem, group 5-16”; “Vegetable, cucurbit, group 9”; and “Vegetable, root, except sugar beet, subgroup 1B”; and

ii. Remove the entries “*Brassica*, head and stem, subgroup 5A”; “*Brassica*, leafy greens, subgroup 5B”; “Cucumber”; “Leaf petioles, subgroup 4B”; “Leafy greens, subgroup 4A, except head lettuce and leaf lettuce”; “Lettuce, head”; “Lettuce, leaf”; “Pea and bean, dried shelled, except soybean, subgroup 6C, except cowpea, field pea, and grain lupin”; “Pea and bean, succulent shelled, subgroup 6B, except cowpea”; “Turnip, greens”; “Vegetable, cucurbit, group 9, except cucumber”; “Vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip”.

b. Remove from the table in paragraph (d) the entries “Beet, garden, roots”; “Cowpea, seed”; “Lupin, grain, grain”; “Pea field, seed”; “Radish, roots”; and “Turnip, roots”.

The additions read as follows:

**§ 180.589 Boscalid; tolerances for residues.**

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

Commodity	Parts per million
* * * * *	
<i>Brassica</i> , leafy greens, subgroup 4-16B, except watercress	60
* * * * *	
Celtuce	45
* * * * *	
Fennel, Florence	45
* * * * *	
Kohlrabi	6.0
Leaf petiole vegetable subgroup 22B	45

Leafy greens subgroup 4-16A	70
* * * * *	
Pea and bean, dried shelled, except soybean, subgroup 6C	2.5
Pea and bean, succulent shelled, subgroup 6B	0.60
* * * * *	
Vegetable, <i>Brassica</i> , head and stem, group 5-16	6.0
* * * * *	
Vegetable, cucurbit, group 9	3.0
* * * * *	
Vegetable, root, except sugar beet, subgroup 1B	2.0
* * * * *	

\* \* \* \* \*

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