



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0600; FRL-9968-95]

Boscalid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of boscalid in or on vegetable, legume, edible-podded subgroup 6A. BASF Corporation 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-2016-0600, 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 FFDCFA 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-2016-0600 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-2016-0600, 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 July 26, 2017 (82 FR 34664) (FRL-9963-50), 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 6E8503) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research

Triangle Park, NC 27709. The petition requested that 40 CFR 180.589 be amended by increasing the existing tolerance for residues of the fungicide boscalid, 3-pyridinecarboxamide,2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl), in or on vegetable, legume, edible podded subgroup 6A at from 1.6 parts per million (ppm) to 5.0 ppm. This document referenced a summary of the petition prepared by BASF 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.

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 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 and Points of Departure*

In the **Federal Register** of March 18, 2015 (80 FR 14009) (FRL-9921-01), EPA published a final rule concerning tolerances for residues of boscalid. The preamble to that rule contains a summary of the toxicological profile and endpoints for assessing risk that EPA is incorporating by reference here, as those elements have not changed.

B. *Exposure Assessment*

The petitioned-for tolerance increase is intended to facilitate imports of commodities in subgroup 6A, rather than accommodate residues resulting from changes in domestic uses; therefore, the only potential impact on the Agency's previous exposure assessment is through consumption of imported food containing boscalid residues. To assess the new dietary exposure levels, 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:

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.

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 used some percent crop treated (PCT) information as described below.

Cancer. As discussed in Unit III.A. of the March 18, 2015 Federal Register, 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.

Anticipated residue and percent crop treated (PCT) information. 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 used the following chronic PCT for existing uses:

Almonds 45%; apples 15%; apricots 30%; green beans 5%; blueberries 35%; broccoli 2.5%; brussels sprouts 2.5%; cabbage 5%; caneberries 45%; cantaloupes 5%; carrots 20%; cauliflower 2.5%; celery 10%; cherries 50%; chicory 5%; cucumbers 5%; dry beans/dry peas 5%; garlic 5%; grapes 30%; hazelnuts 5%; lemons 2.5%; lettuce 30%; nectarines 15%; onions 25%; oranges 1%; peaches 25%; peanuts 1%; pears 20%; green peas 1%; peppers 2.5%; pistachios

30%; plums/prunes 5%; potatoes 25%; pumpkins 10%; squash 5%; strawberries 60%; sweet corn 1%; tomatoes 2.5%; walnuts 5%; and watermelons 25%.

In most cases, EPA uses available data from the 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 six years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 2.5%. The maximum PCT figure is the highest observed maximum value reported within the most recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except for situations in which the maximum PCT is less than 2.5%. In cases where the estimated value is less than 2.5% but greater than 1%, the average and maximum PCT used are 2.5%. If the estimated value is less than 1%, 1% is used as the average PCT and 2.5% is used as the maximum PCT.

The Agency believes that the three conditions discussed above 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 may be applied in a particular area.

Because this tolerance increase does not impact drinking water or residential exposures, the drinking water and non-dietary exposure discussions from the March 18, 2015 **Federal Register** continue to be valid. Those assumptions were used to assess aggregate exposure for this tolerance action, and EPA incorporates them here by reference. Moreover, the current action does not impact the Agency's previous conclusions on cumulative effects; therefore, EPA incorporates the cumulative effects section from the March 18, 2015 **Federal Register** as well.

C. Safety Factor for Infants and Children

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

2. *Conclusion.* The finding for the FQPA SF in the March 18, 2015 rule remains valid for this action. Therefore, for the reasons stated in the March 18, 2015 **Federal Register**, 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 residential handler inhalation exposure.

D. 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 12% of the cPAD for the general U.S. population and 27% of the cPAD for all infants (less than 1 year old), the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of boscalid is not expected.

3. *Short-term and intermediate-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, which the Agency previously assessed and discussed in the March 18, 2015 **Federal Register**. The preamble to the March 18, 2015 rule concluded that there were no short-term risks of concern. Because the chronic dietary exposure has only increased potential chronic risk

1% of the cPAD to 27% of the cPAD, which is still well below EPA's level of concern for chronic risk, and there is no change to the domestic use pattern to impact the non-occupational exposure, EPA concludes that the increase in dietary exposure will not meaningfully impact the aggregate risk and the short-term risk will continue to be below the Agency's levels 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.* As discussed in Unit III.A. of the March 18, 2015 **Federal Register**, 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

An adequate gas chromatography/mass spectrometric detection (GC/MS) method (Method D0008) using selected ion monitoring (SIM) of major ions is available for enforcing boscalid tolerances in plant commodities, and an adequate GC/electron capture detection method (ECD) (Method DFG S19) is available for enforcing the tolerances in livestock commodities. The validated limit of quantitation (LOQ) for boscalid residues in most plant matrices is 0.05 ppm. These methods have been found adequate by the Analytical Chemistry Branch (ACB) of BEAD. Residues of boscalid and its metabolite M510F01 were not adequately recovered using the multiresidue methods.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by 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 has established MRLs for boscalid in or on vegetable, legume, edible-podded subgroup 6A at 3.0 ppm. These MRLs are different than the tolerances established for boscalid

in the United States. The registrant has petitioned the EPA to increase the existing tolerance level for edible-podded legume vegetable subgroup 6A from 1.6 ppm to 5.0 ppm in order to harmonize with MRL established by the European Union of 5.0 ppm. This is not anticipated to cause a trade irritant since the CODEX MRL will be lower than the U.S. tolerance, and CODEX countries will still be able to export to the U.S. For these reasons, EPA has determined it is appropriate to amend the tolerance for residues of boscalid on edible podded legume vegetable subgroup 6A as petitioned from 1.6 ppm to 5.0 ppm.

V. Conclusion

Therefore, a tolerance is established for residues of boscalid, boscalid, 3-pyridinecarboxamide,2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl), in or on vegetable, legume, edible podded subgroup 6A at 5.0 ppm.

VI. Statutory and Executive Order Reviews

This action amends a tolerance under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), or 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 5, 2017.

Daniel Kenny,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.589, revise the entry for “Vegetable, legume, edible podded subgroup 6A” in the table in paragraph (a)(1) to read as follows:

§ 180.589 Boscalid; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * *	* * *
Vegetable, legume, edible podded subgroup 6A	5.0
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