

DATES: *Effective date:* October 16, 2009.

FOR FURTHER INFORMATION CONTACT: Marilyn Redman at 301-837-3174.

SUPPLEMENTARY INFORMATION: The location of NARA's Kansas City regional archives has changed. This document updates 36 CFR Part 1253 with the new location information. Also, NARA is changing the hours for our Kansas City location and existing New York City location.

NARA published a proposed rule on June 12, 2009, in the **Federal Register** (74 FR 27956) for a 60 day public comment period. We notified several of our constituent groups by e-mail and provided a notice about the proposed rule on our Web site, <http://www.archives.gov>. The public comment period closed on August 11, 2009; we received one public comment. The commenter remarked only about the change in hours and agreed that the change made sense if that would assist visitors. The commenter added that it would be helpful to have one night during the week or longer hours on Saturday for those who cannot visit during conventional business hours. The comment does not specify whether the concern relates to either, or to both, research locations. If a need for additional hours becomes evident in the future, and available resources support extending our hours, we will further explore the matter. As a result, we have made no changes in this final rule.

This rule is not a significant regulatory action for the purposes of Executive Order 12866 and has not been reviewed by the Office of Management and Budget (OMB). As required by the Regulatory Flexibility Act, it is hereby certified that this rule will not have a significant impact on a substantial number of small entities because this rule applies to individual researchers. This rule does not have any federalism implications. This rule is not a major rule as defined in 5 U.S.C. Chapter 8, Congressional Review of Agency Rulemaking.

List of Subjects in 36 CFR Part 1253

Archives and records.

■ For the reasons set forth in the preamble, NARA amends part 1253 of title 36, Code of Federal Regulations, as follows:

PART 1253—LOCATIONS OF RECORDS AND HOURS OF USE

■ 1. The authority citation for part 1253 continues to read as follows:

Authority: 44 U.S.C. 2104(a).

■ 2. Amend § 1253.7 by revising paragraphs (c) and (g) as follows:

§ 1253.7 Regional Archives.

* * * * *

(c) NARA—Northeast Region (New York City) is located at 201 Varick Street, 12th Floor, New York, NY 10014-4811 (entrance on Houston Street, between Varick and Hudson). The hours are 9 a.m. to 5 p.m., Monday through Friday. The telephone number is 212-401-1620 or Toll Free 1-866-840-1752.

* * * * *

(g) NARA—Central Plains Region (Kansas City) is located at 400 West Pershing Road, Kansas City, MO 64108. The hours are 8 a.m. to 4 p.m., Tuesday through Saturday. The telephone number is 816-268-8000.

* * * * *

Dated: September 11, 2009.

Adrienne C. Thomas,

Acting Archivist of the United States.

[FR Doc. E9-22403 Filed 9-15-09; 8:45 am]

BILLING CODE 7515-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0624; FRL-8431-1]

Boscalid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of boscalid in or on coffee, green bean imported and amends the tolerance for banana, imported. BASF, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation is also removing a tolerance for cucumber, and one tolerance for vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip which are superceded with higher tolerances formerly published in the **Federal Register** of March 28, 2008 (73 FR 16553) (FRL-8354-4).

DATES: This regulation is effective September 16, 2009. Objections and requests for hearings must be received on or before November 16, 2009, 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: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0624. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>.

Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Bryant Crowe, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-0025; e-mail address: crowe.bryant@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access

this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2008–0624 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before November 16, 2009.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0624, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerances

In the **Federal Register** of November 5, 2008 (73 FR 65849) (FRL–8385–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of

pesticide petitions (PP 8E7366, PP 8E7367) by BASF Corporation, P.O. Box 13528, 26 Davis Drive, Research Triangle, NC 27709. The petitions requested that 40 CFR 180.589 be amended by increasing the tolerance for residues of the fungicide boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro(1,1'-biphenyl))-2-yl, in or on banana from 0.2 parts per million (ppm) to 0.5 ppm (PP 8E7366), and establishing a tolerance for coffee, green bean at 0.05 ppm (PP 8E7367). That notice referenced a summary of the petitions prepared by BASF Corporation, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. One comment was received from a private citizen. EPA’s response to comment is discussed in Unit IV.C.

Additionally, in this action EPA is correcting an error in a prior tolerance rulemaking for boscalid (73 FR 16553) (March 28, 2008). In that action, EPA amended the boscalid tolerances for cucumber and vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip by increasing the level of each of those tolerances. Inadvertently, however, the revised tolerance levels were added to the CFR without removing the prior tolerances. This action removes the prior tolerances.

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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the petitioned-for tolerances for residues of boscalid on banana, imported at 0.40 ppm, and coffee, green bean, imported at 0.05 ppm. EPA’s assessment of exposures and risks associated with establishing tolerances follow.

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.

Boscalid has low acute toxicity via the oral, dermal, and inhalation routes of exposure and is not an eye or skin irritant. Dermal sensitization could not be determined because the skin sensitization study was inadequate. The target organs for boscalid are the thyroid and liver.

An acute endpoint was not selected because no adverse effects attributable to a single exposure to boscalid were seen in the database, including the developmental toxicity studies. The chronic dietary, incidental oral, dermal, and inhalation endpoints were all selected from three co-critical studies: The chronic rat study, the rat carcinogenicity study, and a 1-year feeding study in dogs. The dose selected for regulation of oral, dermal, and inhalation risk at all durations, for all populations, is the “no-observed-adverse-effect level” of 21.8 milligrams/kilogram/day (mg/kg/day) based on thyroid and hepatic toxicity seen in rats and dogs at higher dose levels.

Boscalid is classified as exhibiting “suggestive evidence of carcinogenicity.” Evidence of carcinogenicity was seen in males (significant trend, and pair-wise at the high dose) and in females (trend only) in rats or mice or both; however, in both sexes no malignancies were seen. Only benign tumors were observed, and these occurred at dose levels above the dose level used to establish the chronic population adjusted dose (cPAD). Additionally, there is no concern for mutagenicity. EPA has concluded that the cPAD is protective of any tumor response seen in the boscalid cancer studies.

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> in the “Boscalid – Human Health Risk Assessment of the Proposed Food Use of the Fungicide on Imported Coffee” on pages 16–21 in docket ID number EPA–HQ–OPP–2008–0624.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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>; <http://www.epa.gov/oppfead1/trac/science>, and <http://www.epa.gov/pesticides/trac/science/aggregate.pdf>.

A summary of the toxicological endpoints for boscalid used for human risk assessment can be found at <http://www.regulations.gov> in the “Boscalid – Human Health Risk Assessment of the Proposed Food Use of the Fungicide on

Imported Coffee” on pages 6–7 in docket ID number EPA–HQ–OPP–2008–0624.

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 part 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 was not conducted.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. As to residue levels in food, EPA made the following assumption for the chronic exposure assessments: The assessment was based on tolerance level residues for existing uses, recommended tolerance levels for banana and coffee, and 100% crop treated assumptions.

iii. *Cancer.* For the reasons set forth in Unit II.A., EPA has concluded that the cPAD is protective of any cancer effects with boscalid. EPA’s estimate of chronic exposure as described above is relied upon to evaluate whether any exposure could exceed the cPAD and thus pose a cancer risk.

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://www.epa.gov/oppfead1/models/water/index.htm>.

The current requests for an increased tolerance in banana, and a new use on coffee, do not affect the estimated drinking water concentrations (EDWCs) because both requests are for tolerances on imported commodities. As a result, the EDWCs used in the previous

assessment “Boscalid - Human Health Risk Assessment to support proposed new uses on fresh herbs (herbs subgroup 19A), avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, star apple and cotton” on page 15 in docket ID number EPA–HQ–OPP–2008–0624 at <http://www.regulations.gov> were used in this assessment as well. The EDWCs were based on the turf use.

Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, the EDWCs of boscalid for chronic exposures for non-cancer assessments are estimated to be 29.6 ppb for surface water and 0.63 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 0.029 ppm 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, strawberries, caneberries, and tree fruit grown at “U-pick” farms and orchards. EPA assessed residential exposure using the following assumptions: Dermal post-application exposure for golfers exposed to treated turf. The duration of exposure is anticipated to be short-term.

Based on the low vapor pressure of boscalid (7×10^{-9} hPa), the outdoor nature of the uses, and the weight of evidence from available residue studies, the Agency does not anticipate post-application inhalation exposures from the currently approved uses of boscalid.

In addition, U-pick activities are considered to be one-time (<1 day) events. As no adverse effects were seen in the boscalid toxicity database resulting from a single exposure to the chemical a post-application exposure assessment is not required for this scenario.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA 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://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.* In the 2-generation reproduction study in rats, body weight effects were seen in the mid-and-high doses in the second generation male pups. However, the degree of concern is low for the quantitative evidence of susceptibility seen in this study, since the body weight effects were seen in only one sex and only after dosing for two generations. There is a clear NOAEL for the body weight effects seen in the rat 2-generation reproduction study and EPA is regulating based on a POD below where these effects are seen.

In the developmental neurotoxicity study, transient body weight effects were seen in one sex at postnatal days 1–4 with the animals recovering by postnatal day 11. Body weight effects were also seen in the high dose, which was the limit dose. The degree of concern for these effects are low since the effects are either transient in nature or occurred at the limit dose and EPA is regulating based on a POD below where these effects are seen.

While qualitative sensitivity was seen in the rabbit developmental study, the fetal effects were seen only at the limit dose in the presence of maternal toxicity. Further, since EPA is regulating

based on a POD which is an order of magnitude below where these effects are seen in the rabbit developmental study, EPA concludes that the qualitative sensitivity evidenced in the fetuses in the rabbit developmental study does not require retention of the 10X children's safety factor.

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 boscalid is adequate for risk assessment, however an immunotoxicity study (OPPTS Guideline 870.7800) in rats and/or mice is required under the new 40 CFR part 158 data regulations. No indication of immunotoxicity was observed in the toxicity database; therefore, an additional 10X database uncertainty factor (UF) is not warranted.

ii. There is no indication that boscalid is a neurotoxic chemical and there is no need for additional UFs to account for neurotoxicity. There is no evidence of neurotoxicity in the acute subchronic, or developmental neurotoxicity studies. The toxicity studies for boscalid demonstrate that, in general, the chemical has low mammalian toxicity, and the database reveals no reproductive, developmental, or developmental neurotoxicity concerns.

iii. Data involving the testing of young animals did show increased quantitative sensitivity in the young with regard to body weight effects, and qualitative sensitivity was seen in one developmental study. However, clear NOAELs were identified for all of these effects. Moreover, the body weight effects at the LOAELs in these studies were either transient or inconsistent, and qualitative sensitivity occurred at the limit dose in the presence of maternal toxicity. Additionally, EPA is regulating based on a POD below where these effects are seen. EPA concludes that there are no residual uncertainties for pre- and/or post-natal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. EPA has conservatively estimated human exposure to boscalid, relying on worst case exposures in food (assuming all registered crops contain residues at the tolerance level), and conservative models, as well as pesticide-specific data, in estimating exposure from residues in drinking water, and from residential uses. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute 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 33% of the cPAD for children 1 to 2 years of age, 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 use(s) 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 aggregated result in aggregate MOEs of 950 for the U.S. population, 1,200 for females 13–49 years old, and 1,300 for youth 13–19 years old.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water

(considered to be a background exposure level). Because no intermediate term, non-occupational exposures are anticipated from the use of boscalid, an intermediate-term aggregate risk assessment is not required for boscalid.

5. *Aggregate cancer risk for U.S. population.* Boscalid is classified as exhibiting “suggestive evidence of carcinogenicity.” Evidence of carcinogenicity was seen in males (significant trend, and pair-wise at the high dose) and in females (trend only); however, in both sexes no malignancies were seen. Only benign tumors were observed, and these occurred at dose levels above the dose level used to establish the cPAD. Additionally, there is no concern for mutagenicity.

Quantification of human cancer risk is not required. Aggregate cancer exposure and risk are not of concern. Therefore, an aggregate risk assessment was not conducted.

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 methodologies high performance liquid chromatography/ultra violet (HPLC/UV), and liquid chromatography/mass spectrometry/tandem mass spectrometry (LC/MS/MS) are available to enforce the tolerance expressions. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

The Codex Alimentarius Commission has established a MRL for residues of boscalid in or on banana at 0.2 ppm, which is equivalent to the current U.S. tolerance. However, the recommended U.S. tolerance is higher than the Codex MRL. In the submitted field trials, residues above the Codex MRL were observed. As a result, it is not possible to harmonize the banana tolerance with the Codex MRL. There is a Codex Maximum Residue for the residues of boscalid in/on coffee beans at 0.05 ppm.

C. Response to Comments

One anonymous public comment was received on November 5, 2008. The commenter claimed that there was

suggestive evidence of carcinogenic effects from boscalid but that EPA had not assessed these effects. In response, EPA notes that, for the reasons set forth in Unit II.A., EPA has concluded that boscalid cPAD provides an adequate margin of safety with regard to the benign tumors seen in cancer studies with boscalid.

D. Revisions to Petitioned-For Tolerances

The petition requested that 40 CFR 180.589 be amended by increasing the tolerance for residues of boscalid in or on banana from 0.2 ppm to 0.5 ppm. Based on the output from the tolerance spreadsheet, the Agency recommends in favor of the establishment of an import tolerance of 0.40 ppm.

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today’s technical correction final without prior proposal and opportunity for comment, because EPA is correcting an error in a prior tolerance rulemaking for boscalid (73 FR 16553) (March 28, 2008). In that action, EPA amended the boscalid tolerances for cucumber and vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip by increasing the level of each of those tolerances. Inadvertently, however, the revised tolerance levels were added to the CFR without removing the prior tolerances. This action removes the prior tolerances. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

V. Conclusion

Therefore, tolerances are amended for residues of boscalid, in or on banana, imported at 0.40 ppm, and established for coffee, green bean, imported at 0.05 ppm. Additionally, the duplicate boscalid tolerances for cucumber at 0.20 ppm, and vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip at 0.7 ppm are removed correcting the error in which these superceded tolerances were not deleted despite their amendment.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 section 408(d) of FFDCA, 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 final rule 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 section 408(n)(4) of FFDCA. 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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 of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 25, 2009.

Lois A. Rossi,

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, the table to paragraph (a)(1) is amended by alphabetically adding an entry for "coffee, green bean, imported", by revising the entry for "banana, import" and by removing the entry for "cucumber" with the limit of 0.20 ppm and the entry for "vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip" with the limit of 0.7 ppm. The added and revised entries read as follows:

§ 180.589 Boscalid; tolerances for residues.

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

| Commodity | Parts per million |
|-------------------------------------|-------------------|
| * * * * * | * |
| Banana, import \\\ * | 0.40 |
| Coffee, green bean, import \\\ .. * | 0.05 |

¹No US registrations as of September 16, 2009.

* * * * *
[FR Doc. E9-22163 Filed 9-15-09; 8:45 am]
BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0002; FRL-8434-1]

Acetochlor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acetochlor, including its metabolites and degradates, in or on cotton, gin byproducts; cotton, undelinted seed; soybean, meal; and soybean, seed. Monsanto Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also removes the existing tolerance for indirect or inadvertent residues of acetochlor on soybean, seed. **DATES:** This regulation is effective September 16, 2009. Objections and requests for hearings must be received on or before November 16, 2009, 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: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0002. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: stanton.susan@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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