available and applicable voluntary consensus standards.

The requirements of section 12(d) of the NTTAA do not apply because this rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. As explained above, EPA has approved Pennsylvania's antidegradation policy because it is consistent with 40 CFR 131.12. This rule withdraws a redundant antidegradation policy.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective on June 28, 2010.

List of Subjects in 40 CFR Part 131

Environmental protection, Antidegradation, Water quality standards.

Dated: May 21, 2010.

Lisa P. Jackson,

Administrator.

■ For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 131—WATER QUALITY STANDARDS

■ 1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

§ 131.32 [Removed and Reserved]

■ 2. Section 131.32 is removed and reserved.

[FR Doc. 2010–12933 Filed 5–27–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0268; FRL–8826–4]

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. This regulation additionally revises established tolerances in or on fruit, stone, group 12; hog, fat; poultry, fat; and poultry, meat byproducts. Finally, this regulation deletes the time-limited tolerance on tangerine as it expired on December 31, 2008. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 28, 2010. Objections and requests for hearings must be received on or before July 27, 2010, 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–2009–0268. 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: Shaja Joyner, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *joyner.shaja@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 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 *www.gpoaccess.gov/ecfr*.

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–2009–0268 on 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 July 27, 2010. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0268, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 19, 2009 (74 FR 41898) (FRL–8426–7), 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 9F7527 and PP 9F7529 by BASF Corporation, Research Triangle Park, NC 27709. PP 9F7527, which was incorrectly written as PP 9F7529 in the notice, 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 alfalfa, forage at 35 part per million (ppm); alfalfa, hay at 85 ppm; and citrus, crop group 10 at 2 ppm. PP 9F7529 requested to increase the existing tolerance in or on fruit, stone, group 12 from 1.7 ppm to 5 ppm. That notice 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.

Based upon review of the data supporting the petition, EPA has revised several proposed tolerances and has determined that separate tolerances are necessary for citrus, dried pulp and citrus, oil. The Agency has also revised several established livestock commodities. Finally, EPA has revised the tolerance expression for all established commodities to be consistent with current Agency policy. 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 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 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.

Boscalid has low acute toxicity via the oral, dermal, and inhalation routes of exposure, and it is not an eye or skin irritant. Following subchronic and chronic exposure to boscalid, the liver and thyroid appeared to be the target organs in several species. In mice, subchronic exposure to boscalid resulted in increased liver weights and an increased incidence of marked fatty changes in the liver. Subchronic and chronic studies in dogs resulted in increases in alkaline phosphatase levels as well as hepatic weights. In subchronic and chronic studies in rats, thyroid changes (including increases in weights and incidences of follicular cell hyperplasia and hypertrophy) were considered to have been the result of liver adaptive responses. Additionally, in three mechanistic rat studies, increases in liver microsomal activity, induction of total cytochrome P450 activity, and disruption of thyroid homeostasis (by decreasing circulating T3 and T4 and increasing TSH resulting from hepatic microsomal glucuronyltransferase) were noted. The liver and thyroid effects were reversed with the cessation of test article administration.

In the rabbit developmental toxicity study, abortions and early deliveries were observed in at the highest dose tested. Decreased pup body weights and/or body weight gains were noted in both the 2-generation reproductive toxicity study in rats and in the rat developmental neurotoxicity (DNT) study at a level that did not induce parental toxicity.

In two chronic/carcinogenicity studies in rats that were assessed together, statistically significant increases in thyroid follicular cell adenomas and significant differences in a pair-wise comparison with the controls were noted in males; thyroid hypertrophy and hyperplasia of follicular cells, as well as increased thyroid weights and mechanistic data were also noted. Female rats exhibited a slightly significant increase in thyroid follicular cell adenomas in these studies. A carcinogenicity study in mice

showed no evidence of tumor formation in either sex, and no evidence of malignancies or mutagenicity was found in the toxicity database for boscalid. Based on the overall weak evidence of carcinogenic effects, EPA has classified boscalid as having suggestive evidence of carcinogenicity.

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 document: "Boscalid. Human Health Risk Assessment for Proposed Use on Alfalfa and Citrus (Crop Group 10), and for Proposed Increase in Tolerance on Stone Fruits (Crop Group 12)." Pages 41–44 in docket ID number EPA–HQ–OPP–2009–0268.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level-generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for boscalid used for human risk assessment is shown in Table 1 of this unit.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BOSCALID FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–50 years of age; and general population including infants and children)	No appropriate endpoint attributable to a single dose was available in the current database, including the developmental toxicity studies. Therefore, an aRfD and aPAD were not established for any population.		
Chronic dietary (All populations)	NOAEL = 21.8 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.218 mg/kg/day cPAD = 0.218 mg/kg/day	Combined results of chronic rat, carcinogenicity rat, and 1–year dog studies LOAEL = 57 mg/kg/day based on liver and thyroid effects
Dermal short-term (1 to 30 days)	Dermal (or oral) study NOAEL = 21.8 mg/kg/day (dermal absorption rate = 15%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Combined results of chronic rat, carcinogenicity rat, and 1–year dog studies LOAEL = 57 mg/kg/day based on liver and thyroid effect.
Cancer (Oral, dermal, inhalation)	Classification: Suggestive evidence of carcinogenicity. The cRfD is protective of cancer effects. Quantification of human cancer risk is not necessary.		

UF_A = extrapolation from animal to human (interspecies).
UF_H = potential variation in sensitivity among members of the human population (intraspecies).
FQPA SF = Food Quality Protection Act Safety Factor.
PAD = population adjusted dose (a = acute, c = chronic).
RfD = reference dose.
MOE = margin of exposure.
LOC = level of concern.

Additional information regarding the toxicological endpoints for boscalid used for human risk assessment can be found at *http://www.regulations.gov* in docket ID numbers EPA–HQ–OPP–2009–0268 and EPA–HQ–OPP–2005–0145.

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 the food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA utilized tolerance-level residues and assumed 100 percent crop treated (PCT) data for all commodities.

iii. *Cancer.* As discussed in Unit III.A., EPA has classified boscalid as having suggestive evidence of carcinogenicity due to some evidence of

thyroid follicular cell adenomas in male and female rats. Nonetheless, EPA concluded that the cPAD would be protective of these effects based on the following:

The adenomas occurred at dose levels above the level used to establish the cPAD, statistically significant increases were only seen for benign tumors (adenomas) and not for malignant ones (carcinomas), the increase in adenomas in females was slight, and there was no concern for mutagenicity. 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.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for boscalid. Tolerance level residues or 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://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of boscalid for chronic exposures for non-cancer assessments are estimated to be 29.6 parts per billion (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 29.6 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 use on turf at golf courses and for use on several fruit commodities at "pick-your-own" (PYO) farms and orchards; therefore, post-application exposure to golfers and people harvesting fruit at PYO farms and orchards is possible. EPA assessed residential exposure using the following assumptions: For adult and adolescent (12 years of age or older) golfers, short-term post-application dermal exposure to turf treated with boscalid was assessed. PYO activities may result in potential acute post-application exposure to boscalid; however, because no adverse effects were noted in the boscalid toxicity database resulting from a single exposure to the chemical, a post-application exposure and risk assessment is not necessary for this scenario. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

EPA also notes that while adolescents are likely to represent the vast majority of youth who play golf on a routine basis, it is possible for younger children (less than 12 years old) to be exposed to golf course turf that has been treated with boscalid. However, assessing risk for younger golfers is difficult because of the uncertainties associated with the extrapolation of adult dermal exposure data and because of the increased likelihood of other behaviors that might contribute to exposure, such as incidental oral exposure resulting from contact with treated turf. Therefore, younger golfers were assessed qualitatively for this exposure scenario after selecting an appropriate target age of 5 years old to assess risk. The surface area to body weight ratio (SA/BW) for male children, when calculated and compared to that of the average adult, was found to be approximately 70% greater. Based on this parameter alone, the exposure to children could be almost twice that of the adult golfer; however, younger golfers are not expected to use the golf course for the same length of time as an adult. The shorter duration on the golf course for younger golfers offsets the higher SA/BW; therefore, risks from short-term post-application exposures to young golfers are likely to be similar to risks for adult golfers.

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://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*. The prenatal and postnatal toxicology database for boscalid includes rat and rabbit prenatal developmental toxicity studies, a 2-generation reproductive toxicity study in rats, and a DNT study in rats. No qualitative or quantitative evidence of increased susceptibility was noted in the developmental toxicity study in rats. However, 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. Also, 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 were seen.

In the rat DNT 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 is low since the effects were either transient in nature or occurred at the limit dose, and EPA is regulating based on a POD below where these effects were seen. In the rabbit developmental study there was evidence of qualitative sensitivity;

however, 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 were seen in the rabbit developmental study, EPA concludes that there is a low degree of concern for the qualitative sensitivity evidenced in the fetuses in the rabbit developmental 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. That decision is based on the following findings:

i. The toxicity database for boscalid is complete, except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. The available data for boscalid show no evidence of treatment-related effects on the immune system, and the Agency does not believe that conducting an immunotoxicity study will result in a lower point of departure than currently selected for overall risk assessment. Therefore, an additional database uncertainty factor to account for potential immunotoxicity does not need to be applied.

ii. A rat DNT study is available which provides no indication that boscalid is a neurotoxic chemical, and there is no evidence of reproductive or developmental neurotoxicity in the toxicity database.

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 prenatal and/or postnatal 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 adult golfers, which is expected to be similar to potential 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-term, intermediate-term, 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 37% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of 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 an aggregate MOE of 840 for the general U.S. population and an aggregate MOE of 1,140 for youth (13–19 years old). As described above, the level of risk to younger golfers is expected to be similar. 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 discussion in Unit III.A., EPA has concluded that the cPAD is protective of possible cancer effects. Given the results of the chronic risk assessment above, 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 gas chromatography with mass spectrometric detection (GC/MS) and GC with electron capture (EC) methods are available to enforce boscalid tolerances in or on plant and livestock commodities, respectively. 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

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 U.N. 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.

There are currently no Codex, Canadian, or Mexican MRLs for residues of boscalid in or on alfalfa forage, alfalfa hay, or citrus fruits. However, there is a Codex MRL for stone fruits at 3 ppm and a Canadian MRL for stone fruits at 1.7 ppm. At this time, the revised U.S. tolerance on fruit, stone, group 12 at 3.5 ppm cannot be harmonized because residue field trial data support a tolerance that is higher than the Codex and Canadian MRLs. Codex and Canadian MRLs for boscalid also exist for various livestock commodities. However, because Codex and Canadian MRLs on boscalid do not exist for some animal feed commodities which have U.S. tolerances, the dietary burden of boscalid is higher for animals in the U.S., and U.S. livestock tolerances cannot be harmonized with equivalent Codex or Canadian MRLs at this time.

C. Revisions to Petitioned-For Tolerances

Based on analysis of the data supporting the petition, EPA has revised the proposed tolerances on alfalfa, forage from 35 ppm to 30 ppm; alfalfa, hay from 85 ppm to 65 ppm; fruit, citrus, group 10 from 2.0 to 1.6 ppm; and fruit, stone, group 12 from 5.0 to 3.5 ppm. The Agency has also determined that individual tolerances are necessary for citrus, dried pulp at 4.5 ppm; and citrus, oil at 85 ppm because boscalid residues concentrate in these commodities. EPA revised these tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*. Because tolerances are being established on alfalfa forage and alfalfa hay under 40 CFR 180.589(a)(1), which applies to residues resulting from intentional or inadvertent use, EPA has also revised current inadvertent residue tolerance entries so that they exclude alfalfa, as follows: animal feed, nongrass, group 18, forage, except alfalfa and animal feed, nongrass, group 18, hay, except alfalfa.

Additionally, EPA is modifying several tolerances for secondary residues in animal commodities. In conjunction with assessing potential residues in animal commodities from the proposed and established uses of boscalid, EPA has determined that the established tolerances for secondary residues in or on poultry and hog commodities need to be raised. Therefore, the Agency is increasing the established tolerances for hog, fat from 0.10 ppm to 0.20 ppm; poultry, fat from 0.05 ppm to 0.20 ppm; and poultry, meat byproducts from 0.10 to 0.20 ppm. Finally, EPA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of boscalid not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-*N*-(4′-chloro[1,1′-biphenyl]-2-yl), in or on alfalfa, forage at 30 ppm; alfalfa, hay at 65 ppm; fruit, citrus, group 10 at 1.6 ppm; citrus, dried pulp at 4.5 ppm; and citrus, oil at 85 ppm. Additionally, previously established tolerances are revised for fruit, stone, group 12 at 3.5 ppm; hog, fat at 0.20 ppm; poultry, fat at 0.20 ppm; and poultry, meat byproducts at 0.20 ppm. Finally, this regulation deletes a time-limited tolerance on tangerine at 2.0 ppm, as it expired on December 31, 2008.

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 tolerances 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: May 18, 2010

Daniel J. Rosenblatt

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. Section 180.589 is amended by:

i. Revising the introductory text for paragraphs (a)(1) and (a)(2);

ii. Revising the entry for "Fruit, stone, group 12" and alphabetically adding "Alfalfa, forage"; "Alfalfa, hay"; "Citrus, dried pulp"; "Citrus, oil"; and "Fruit, citrus, group 10"; to the table in paragraph (a)(1);

iii. Revising the entries for "Hog, fat"; "Poultry, fat"; and "Poultry, meat byproducts" in the table in paragraph (a)(2);

iv. Revising paragraph (b);

v. Revising paragraph (d) introductory text and revising the entries for "Animal feed, nongrass, group 18, forage" and "Animal feed, nongrass, group 18, hay" in the table in paragraph (d) to read as follows:

§ 180.589 Boscalid; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide boscalid, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only boscalid, 3-pyridinecarboxamide, 2-chloro-*N*-(4′-chloro[1,1'-biphenyl]-2-yl), in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa, forage	30.0
Alfalfa, hay	65.0
* * * * *	
Citrus, dried pulp	4.5
Citrus, oil	85.0
* * * * *	
Fruit, citrus, group 10	1.6
* * * * *	
Fruit, stone, group 12	3.5
* * * * *	

(2) Tolerances are established for residues of the fungicide boscalid, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of boscalid, 3-pyridinecarboxamide, 2-chloro-*N*-(4'-chloro[1,1'-biphenyl]-2-yl), and metabolites 2-chloro-*N*-(4'-chloro-5-hydroxy-biphenyl-2-yl) nicotinamide and glucuronic acid conjugate of 2-chloro-*N*-(4′-chloro-5-hydroxy-biphenyl-2-yl) nicotinamide, calculated as the stoichiometric equivalent of boscalid in or on the following food commodities:

Commodity	Parts per million
* * * * *	
Hog, fat	0.20
* * * * *	
Poultry, fat	0.20
* * * * *	
Poultry, meat byproducts	0.20
* * * * *	

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide boscalid, including its metabolites and degradates, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. Compliance with the tolerance level specified below is to be determined by measuring only boscalid, 3-pyridinecarboxamide, 2-chloro-*N*-(4′-chloro[1,1'-biphenyl]-2-yl). This tolerance will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Endive, Belgian	16	12/31/10

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of the fungicide boscalid, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only boscalid, 3-pyridinecarboxamide, 2-chloro-*N*-(4′-chloro[1,1′-biphenyl]-2-yl), in or on the following commodities:

Commodity	Parts per million
Animal feed, nongrass, group 18, forage, except alfalfa	1.0
Animal feed, nongrass, group 18, hay, except alfalfa	2.0

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0279; FRL–8828-–6]

Prothioconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of prothioconazole and prothioconazole-desthio, calculated as parent in or on grain, cereal, group 15 (except sweet corn, sorghum, and rice), and grain, cereal, forage, fodder and straw, group 16 (except sweet corn, sorghum, and rice) and sweet corn. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 28, 2010. Objections and requests for hearings must be received on or before July 27, 2010, 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–2009–0279. 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: Tawanda Maignan, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8050; e-mail address: *maignan.tawanda@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 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 cite at *http://www.gpoaccess.gov/ecfr*. To access the harmonized test guidelines referenced in this document electronically, please go *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. 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–2009–0279 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 July 27, 2010. 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 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–2009–0279, 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