

and pests, Reporting and recordkeeping requirements.

Dated: December 6, 2006.

Donald R. Stubbs,

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 180.364 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Noni	* * 0.20
Pea, dry	* * 8.0
Safflower	* * 85
Sunflower	* * 85
Vegetable, legume, group 6 except soybean and pea, dry	* * 5.0

(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. [Reserved]

(d) Indirect or inadvertent residues. [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0145; FRL-8107-8]

Boscalid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) in or on leafy

greens subgroup 4A, except head and leaf lettuce, and leafy petioles subgroup 4B. Interregional Research Project No. 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective December 20, 2006. Objections and requests for hearings must be received on or before February 20, 2007, 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-2005-0145. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: madden.barbara@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers;

greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides 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 an electronic copy of this **Federal Register** document through the electronic docket 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 40 CFR part 180 through the Government Printing Office's pilot e-CFR site 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 the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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-2005-0145 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 on or before February 20, 2007.

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 your copies, identified by docket ID number EPA-HQ-OPP-2005-0145, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of June 14, 2006 (71 FR 34342-34344) (FRL-8070-8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E6791) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.589 be amended by establishing tolerances for residues of the fungicide boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl), in or on the raw agricultural commodities as follows: leafy greens subgroup 4A, except head and leaf lettuce at 60 parts per million (ppm) and leaf petioles subgroup 4B at 45 ppm. That notice included a summary of the petition prepared by BASF, the registrant. Comments on the notice of filing were received from one private citizen. EPA's response to these comments is discussed in Unit IV. C.

EPA is also deleting several established tolerances in 180.589(a)(1) that are no longer needed as a result of this action. The revisions to 180.589(a)(1) are as follows:

1. Delete celery at 45 ppm, and replaced with leaf petioles, subgroup, 4B, at 45 ppm.

2. Delete spinach at 60 ppm, and replaced with leafy greens, subgroup 4A, except head and leaf lettuce, at 60 ppm.

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...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm> and <http://www.epa.gov/fedrgstr/EPA-PEST/2003/July/Day-30/p19357.htm>.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for tolerances for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl), in or on the raw agricultural commodities as follows: leafy greens subgroup 4A, except head and leaf lettuce at 60 ppm and leaf petioles subgroup 4B at 45 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances 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. Specific information on the studies received and

the nature of the toxic 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 are discussed in the final rule published in the **Federal Register** of July 30, 2003 (68 FR 44640) (FRL-7319-6) (<http://www.epa.gov/fedrgstr/EPA-PEST/2003/July/Day-30/p19357.htm>).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/pesticides/health/human.htm>.

A summary of the toxicological endpoints for boscalid used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of July 30, 2003 (68 FR 44640) (FRL-7319-6).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established 40 CFR 180.589 (a)(1) for the residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) in or on a variety of raw agricultural commodities. Tolerances have been established under 40 CFR 180.589(a)(2) for the combined residues of the fungicide 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 in or on egg; milk;

and fat, meat and meat byproducts of cattle, goat, hog, horse, poultry, and sheep. Risk assessments were conducted by EPA to assess 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 one-day or single exposure. No such effects were identified in the toxicological studies for boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl); therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: An unrefined, chronic dietary exposure assessment using tolerance-level residues, default processing factors, and assuming 100% crop treated (CT) for all registered and proposed commodities was conducted for the general U.S. population and all population subgroups.

iii. *Cancer.* A quantitative cancer exposure assessment is not necessary because EPA concluded that boscalid is unlikely to pose a carcinogenic risk to humans. This conclusion was based on the following weight of evidence considerations. First, in male Wistar rats, there was a significant trend (but not pairwise comparison) for the combined thyroid adenomas and carcinomas. This trend was driven by the increase in adenomas. Second, in the female rats, there was only a borderline significant trend for thyroid adenomas (there were no carcinomas). Third, the mouse study was negative as were all of the mutagenic tests. Based on this weak evidence of carcinogenic effects, the Agency concluded that boscalid is not expected to pose a carcinogenic risk.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for boscalid in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by

reliance on simulation or modeling taking into account data on the physical 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 and SCI-GROW models, the estimated environmental concentrations (EECs) of boscalid for acute exposures are estimated to be 87.53 parts per billion (ppb) for surface water and 0.63 ppb for ground water. The EECs for chronic exposures are estimated to be 25.77 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 (DEEM-FCID™, Version 2.03). For chronic dietary risk assessment, the annual average concentration of 25.77 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. However, the boscalid registration for turf specifies that this product is intended for golf course use only, and not for use on residential turfgrass or turfgrass being grown for sale or other commercial use such as sod production. Although the registration does not indicate that the product is applied by licensed or commercial applicators, homeowners will not be applying the product to golf courses. Therefore, a risk assessment for residential handler exposure is not required. Boscalid is also registered for use on various fruit crops including U-pick operations. Based on these registrations the EPA determined there are two recreational scenarios associated with boscalid that could lead to non-dietary exposures for adults and children: Adults and youth golfing, and adults and children picking their own fruit.

Because U-pick is a one-time event (duration <1 day) and the Agency found that the oral studies indicated there were no endpoints appropriate to quantitate acute risk, the U-pick exposure was not calculated. Therefore, only non-dietary exposure was estimated for the golfing scenario. The risk assessment was conducted using the following residential exposure assumptions: post-application exposures to individuals that occur as a result of being in an environment that

has been previously treated with a pesticide. Due to residential application practices and the half-lives observed in the turf transferable residue study, intermediate- and long-term post-application exposures are not expected. Only short-term post application exposures are anticipated for golfers. The scenarios likely to result in dermal short-term exposures are as follows: Adult golfer dermal exposure from contacting treated turf, and adolescent golfer dermal exposure from contacting treated turf.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to boscalid and 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 not assumed that boscalid has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that

poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. Prenatal and postnatal sensitivity.

There was no evidence of increased susceptibility in the developmental rat study as no developmental toxicity was seen at the highest dose tested (Limit Dose). There was evidence of qualitative (not quantitative) increased susceptibility in the developmental rabbit study as characterized by an increased incidence of abortions or early delivery at the highest dose tested (1,000 milligram/kilogram/day (mg/kg/day)). It could not be ascertained if the abortions were the result of a treatment-related effect on either the dams, the fetuses or both. There was quantitative evidence of increased susceptibility in the 2-generation reproduction study in rats, where decreases in body weights and body weight gains in male offspring were seen in the F2 generation at a dose that was lower than the dose that induced parental/systemic toxicity. The offspring NOAEL was 10.1/106.8 mg/kg/day in males and females, respectively, and the parental/systemic NOAEL was 101.2/1062.0 mg/kg/day in males and females, respectively. There was quantitative evidence of increased susceptibility in the developmental neurotoxicity study in rats, where decreases in pup body weights (PND 4) and body weight gains (PND 1–4) were seen in the absence of any maternal toxicity. The offspring toxicity NOAEL was 14 mg/kg/day and the maternal NOAEL was 1,442 mg/kg/day.

The degree of concern is low for the qualitative evidence of susceptibility seen in the rabbit developmental study as the increased abortions or early delivery was seen only at the Limit Dose and not at the lower levels (i.e. a high-dose effect) and the abortions may have been due to maternal stress. The degree of concern is also low for the quantitative evidence of susceptibility seen in the 2-generation reproduction study in rats because the decreases in body weight and body weight gains were seen primarily in the F2 generation. These may have been due to exposure of the parental animals to high doses (above the Limit Dose). The dose selected for chronic dietary and non-dietary exposure risk assessments would address the concern for the body weight effects. Finally, the degree of concern is low for the quantitative

evidence of susceptibility seen in the developmental neurotoxicity study because the decreases in pup body weights seen on postnatal days 1 through 4 (and not at any other time periods) were most likely due to maternal toxicity (the maternal animals were exposed to a very high dose exceeding the limit dose, i.e., 1,442 mg/kg/day); and no treatment-related effects on body weight, body weight gain or any other parameter were noted at postnatal day 21.

EPA has concluded that there are no residual uncertainties for pre- and postnatal toxicity as the degree of concern is low for the susceptibility seen in the above studies, and the dose and endpoints selected for the overall risk assessments will address the concerns for the body weight effects seen in the offspring. Although the dose selected for overall risk assessments (21.8 mg/kg/day) is higher than the NOAELs in the 2-generation reproduction study (10.1 mg/kg/day) and the developmental neurotoxicity study (14 mg/kg/day), these differences are considered to be an artifact of the dose selection process in these studies. For example, there is a 10-fold difference between the LOAEL (106.8 mg/kg/day) and the NOAEL (10.1 mg/kg/day) in the two generation reproduction study. A similar pattern was seen with regard to the developmental neurotoxicity study, where there is also a 10-fold difference between the LOAEL (147 mg/kg/day) and the NOAEL (14 mg/kg/day). There is only a 2-3 fold difference between the LOAEL (57 mg/kg/day) and the NOAEL (21.8 mg/kg/day) in the critical study used for risk assessment. Because the gap between the NOAEL and LOAEL in the 2-generation reproduction and developmental neurotoxicity studies was large and the effects at the LOAELs were minimal, the true no-observed-adverse-effect-level was probably considerably higher. Therefore, the selection of the NOAEL of 21.8 mg/kg/day from the 1-year dog study is conservative and appropriate for the overall risk assessments. In addition, the endpoints for risk assessment are based on thyroid effects seen in multiple species (mice, rats and dogs) and after various exposure durations (subchronic and chronic exposures) which were not observed at the LOAELs in either the two-generation reproduction or the developmental neurotoxicity studies.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings: The toxicity database for

boscalid is complete and for the reasons explained above, there is low concern for pre- and postnatal toxicity.

There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. Conservative ground and surface water modeling estimates were used. Similarly conservative residential SOPs were used to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by boscalid.

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* As there were no toxic effects attributable to a single dose, an endpoint of concern was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13–50 years old. No acute risk is expected from exposure to boscalid.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to boscalid from food and water will utilize 11% of the chronic population adjusted dose (cPAD) for the U.S. population, 24% of the cPAD for all infants less than 1 year old, and 38% of the cPAD for children 1–2 years old, the most highly exposed population subgroup. There are no residential uses for boscalid that result in chronic residential exposure to boscalid. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in an aggregate margin of exposure (MOE) of 1,400 for the general U.S. population. This MOE is considered to be representative of young golfers as well since young golfers and adults possess similar body surface area to weight ratios and because the dietary exposure for youth (13–19 years old) is less than that of the general U.S. population. Therefore the short-term aggregate risk and exposure is not of concern to the Agency.

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, boscalid is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the weight of evidence evaluation described previously herein, EPA concluded that boscalid is not expected to pose a carcinogenic risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to boscalid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, method D0008, gas chromatography/mass spectroscopy (GC/MS) for plants and Method DFG S19, gas chromatography/electron-capture detection electron-capture detection (GC/ECD) for animals is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are currently no International or Codex maximum residue levels (MRLs) for boscalid.

C. Response to Comments

Several comments were received from a private citizen objecting to IR-4 proposing to increase the use of this pesticide and establishment of tolerances. The Agency has received these same comments from this commenter on numerous previous occasions. Refer to **Federal Register** 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), 69 FR 63096-63098 (October 29, 2004) for the Agency's response to these objections.

V. Conclusion

Therefore, tolerances are established for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl), regulated chemical, in or on leafy greens subgroup 4A, except head and leaf lettuce at 60 ppm and leaf petioles subgroup 4B at 45 ppm. IR-4 is requesting the establishment of tolerances for leafy greens subgroup 4A, except head and leaf lettuce, and leaf petioles subgroup 4B. The Agency has approved celery and spinach residue data (previously

submitted) and established tolerances for those commodities. These data satisfy the residue data requirements for the requested subgroups, and are accepted as surrogate data for the use of establishing tolerances. Therefore, leafy green subgroup 4A, except head and leaf lettuce, and leafy petioles subgroup 4B will replace the existing tolerances for celery and spinach, respectively.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States,

or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. 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 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: December 8, 2006.

Donald R. Stubbs,

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 in the table to paragraph (a)(1) by removing the commodities "celery" and "spinach" and by adding alphabetically new commodities to read as follows:

§ 180.589 Boscalid; tolerances for residues.

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

Commodity	Parts per million
* * * *	*
Leafy greens, subgroup 4A, except head and leaf lettuce	60
Leafy petioles, subgroup 4B	45
* * * *	*

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0655; FRL-8095-4]

Metconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the fungicide metconazole, 5-[4-

chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazole-1-yl-methyl)cyclopentanol in or on aspired grain fractions; egg; meat, fat and meat by-products of cattle, goat, hog, horse, poultry and sheep; milk; soybean, hulls; soybean, meal; soybean, refined oil; and soybean, seed. This action is associated with EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on soybeans. This regulation establishes a maximum permissible level for residues of metconazole in these food commodities. These tolerances will expire and be revoked on December 31, 2010.

DATES: This regulation is effective December 20, 2006. Objections and requests for hearings must be received on or before February 20, 2007, 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-2006-0655. All documents in the docket are listed on the regulations.gov website. 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 either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Room S-4400, One Potomac Yard (South Bldg.), 2777 South Crystal Dr. Arlington, VA 22202-3553. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Carmen Rodia, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 306-0327; fax: (703) 308-8041; e-mail address: rodia.carmen@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:

- 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 provides 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 an electronic copy of this **Federal Register** document through the electronic docket 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 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by the Food Quality Protection Act of 1996 (FQPA), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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-2006-0655 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 on or before February 20, 2007.

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