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 the FFDCA, such as the exemption from the tolerance requirement 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 the 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.

X. 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: June 20, 2003.

James Jones,

Director, 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), 346(a) and 371.

■ 2. Section 180.1243 is added to subpart D to read as follows:

§ 180.1243 Bacillus subtilis var. amyloliquefaciens strain FZB24; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance for residues of the *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 in or on all agricultural commodities when applied/used in accordance with label directions.

[FR Doc. 03–19134 Filed 7–29–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0246; FRL–7319–6]

Boscalid; 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl); Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) in or on certain commodities and establishes a tolerance for the combined residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) and its metabolites 2-chloro-N-(4'-chloro-5-hydroxy-biphenyl-2-yl)nicotinamide and the glucuronic acid conjugate of 2-chloro-N-(4'-chloro-5-hydroxy-biphenyl-2-yl)nicotinamide in or on certain commodities. BASF Corporation requested 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 July 30, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0246, must be received on or before September 29, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Cynthia Giles-Parker, Registration

Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: 703 305–7740; e-mail address: *giles-parker.cynthia@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, pesticide manufacturer or formulator. Potentially affected entities may include, but are not limited to:

•Crop production (NAICS 111)
•Animal production (NACIS 112)
•Food manufacturer (NAICS 311)
•Pesticide manufacturer (NAICS 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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0246. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This 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.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of February 14, 2003 (68 FR 7542) (FRL–7289– 5), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 1F6313) by BASF Corporation, P.O. Box 13528, Research Triangle Park, North Carolina 27708–2000. That notice included a summary of the petition prepared by BASF Corporation, the registrant. The Agency received one public comment and it, along with the Agency's response, can be found in Unit V.

The petition (1F6313) requested that 40 CFR 180.589 be amended by establishing a tolerance for residues of the fungicide boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl), in or on vegetable, root, subgroup 1B at 1.0 ppm; vegetables, tuberous and corm, subgroup 1C at 0.05 ppm; vegetable, root and tuber, leaves, group 2 at 1.0 ppm; vegetable, bulb, group 3 at 3.0 ppm; vegetable, leafy, group 4, at 11.0 ppm; vegetable, Brassica leafy, subgroup 5A, at 3.0 ppm; vegetable, Brassica leafy, subgroup 5B, at 18.0 ppm; vegetable, legume, group 6, at 2.2 ppm; vegetable, legume foliage, group 7,forage at 1.5 ppm; vegetable,, legume, foliage, group 7, hay at 2.0 ppm vegetable, legume, foliage group 7, vines at 0.05 ppm; vegetable, fruiting, group 8 at 1.0 ppm; vegetable, cucurbit, group 9, at 1.5 ppm; fruit, stone, group 12 at 1.7 ppm; berries, group 13 at 3.5 ppm; nut, tree, group 14 at 0.25 ppm; almond, hulls at 3.0 ppm; pistachio at 0.65 ppm; grain, cereal, group 15 at 0.2 ppm; grain, cereal , forage, fodder, and straw, group 16, forage at 2.0 ppm; grain, cereal , forage, fodder, and straw, group 16, straw at 3.0 ppm; grain, cereal , forage, fodder, and straw, group 16, fodder at 1.5 ppm grass, forage, fodder, and hay, group 17, forage at 2.0 ppm; grass, forage, fodder, and hay, group 17, hay at 8.0 ppm; animal feed, nongrass, group 18, forage at 1.0 ppm; animal feed, nongrass, group 18, hay at 2.0 ppm; animal feed, nongrass, group 18 seed at 0.05 ppm; mint at 30.0 ppm; grape at 3.5 ppm; grape, raisin at 8.5 ppm; strawberry at 1.2 ppm; canola at 3.5 ppm; peanut at 0.05 ppm; peanut, meal at 0.15 ppm; peanut, refined oil at 0.15 ppm; cotton, undelinted seed at 0.05 ppm; cotton, gin byproducts at 0.3 ppm; soybean, seed at 0.1 ppm; soybean, hulls at 0.2 ppm; flax seed at 3.5 ppm and sunflower, seed at 3.5 ppm.

The petition (1F6313) also requested that 40 CFR 180.589 be amended by establishing a tolerance for combined residues of the fungicide 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) and metabolites M510F01 2-chloro-N-(4'-chloro-5-hydroxy-biphenyl-2-yl) nicotinamide and M510F02 glucuronic acid conjugate of M510F01 in or on: Cow milk at 0.10 ppm; cow muscle, at 0.10 ppm; cow, fat at 0.30 ppm; cow, meat byproducts at 0.35 ppm; egg at 0.02 ppm; and poultry muscle, poultry fat, and poultry meat byproducts at 0.05 ppm.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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 the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the 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 the FFDCA, for a tolerance for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) on: Vegetable, root, subgroup 1A, except sugar beet/garden beet/radish/turnip, at 1.0 ppm; vegetable, tuberous and corm, subgroup 1C, at 0.05 ppm; vegetable, bulb, group 3, at 3.0 ppm; lettuce, head at 6.5 ppm; lettuce, leaf at 11.0 ppm; vegetable, Brassica leafy, head and stem, subgroup 5A, at 3.0 ppm; vegetable, Brassica leafy, leafy greens, subgroup 5B, at 18.0 ppm; vegetable, legume, edible-podded, subgroup 6A, at 1.6 ppm; vegetable, legume, succulent shelled pea and bean, subgroup 6B, except cowpea; at 0.6 ppm; vegetable, legume, dried shell pea and bean (except soybean), subgroup 6C, except cowpea, field pea, and grain lupin at 2.5 ppm; vegetable, fruiting, group 8, at 1.2 ppm; vegetable, cucurbit, group 9, except cucumber, at 1.6 ppm; cucumber at 0.20 ppm; fruit, stone, group 12, at 1.7 ppm; berries, group 13, at 3.5 ppm; nut, tree, group 14, at 0.70 ppm; almond, hulls at 3.0 ppm; pistachio at 0.70 ppm; grape at 3.5 ppm; grape, raisin at 8.5 ppm; strawberry at 1.2 ppm; peanut at 0.05 ppm; peanut, meal at 0.15 ppm; peanut, refined oil at 0.15ppm; canola, seed at 3.5 ppm; canola, refined oil at 5.0 ppm; sunflower, seed at 0.60 ppm; peppermint, tops at 30.0 ppm and spearmint, tops at 30.0 ppm.

The Agency also included in this risk assessment dietary exposure (at the anticipated tolerance level) from another pesticide petition (2F6434) for boscalid use on pome fruit and hops. However, the Agency is not establishing tolerances for these commodities at this time, because the residue chemistry review for these commodities is not complete and in fact is not scheduled until the Office of Pesticide Program FY–2004 Workplan.

In addition, also consistent with section 408(b)(2)(D) of the 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 the FFDCA, for a tolerance for residues of boscalid from indirect or inadvertent residues (from rotational crop use), 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) on: Beet, garden, roots at 1.0 ppm; radish, roots at 1.0 ppm; turnip, roots at 1.0 ppm; beet, sugar, roots at 1.0 ppm; vegetable, root and tuber, leaves, group 2 at 1.0 ppm; vegetable, leafy, group 4, except lettuce at 1.0 ppm; vegetable, legume foliage, group 7, forage at 1.5 ppm; vegetable, legume, foliage, group 7, hay at 2.0 ppm; vegetable, legume, foliage group 7, vines at 0.05 ppm; grain, cereal, group 15, at 0.20 ppm; rice, hulls at 0.50 ppm; grain, cereal , forage, fodder, and straw, group 16, fodder at 1.5 ppm; grain, cereal , forage, fodder, and straw, group 16, forage at 2.0 ppm; grain, cereal , forage, fodder, and straw, group 16, straw at 3.0 ppm; grass, forage, fodder, and hay, group 17, forage at 2.0 ppm; grass, forage, fodder, and hay, group 17, hay at 8.0 ppm; grass, forage, fodder, and hay, group 17, straw at 0.30 ppm; grass, forage, fodder, and hay, group 17, seed screenings at 0.20 ppm; animal feed, nongrass, group 18, forage at 1.0 ppm animal feed, nongrass, group 18, hay at 2.0 ppm; animal feed, nongrass, group 18 seed at 0.05 ppm; cotton, undelinted seed at 0.05 ppm; cotton, gin byproducts at 0.30 ppm; soybean, seed, 0.10 ppm; soybean, hulls at 0.20 ppm; cowpea, seed at 0.1 ppm; lupin, grain, grain, at 0.1 ppm; pea, field, seed at 0.1 ppm and flax seed at 3.5 ppm.

Consistent with section 408(b)(2)(D) of the 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 the FFDCA, for a tolerance for combined residues of the fungicide 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) and metabolites M510F01 2-chloro-N-(4'-chloro-5-hydroxy-biphenyl-2-yl) nicotinamide and M510F02 glucuronic acid conjugate of M510F01 in or on milk at 0.10 ppm, cattle, meat at 0.10 ppm, cattle, fat at 0.30 ppm, cattle, meat byproducts at 0.35 ppm, egg at 0.02 ppm, poultry, meat at 0.05 ppm, poultry, fat at 0.05 ppm, poultry, meat byproducts at 0.10 ppm, goat, meat at 0.10 ppm, goat, fat at 0.30 ppm, goat, meat byproducts at 0.35 ppm, hog, meat at 0.05 ppm, hog, fat at 0.10 ppm, hog, meat byproducts at 0.35 ppm, horse, meat at 0.10 ppm, horse, fat at 0.30 ppm, horse, meat byproducts at 0.35 ppm, sheep, meat at 0.10 ppm, sheep, fat at 0.30 ppm, and sheep, meat byproducts at 0.35 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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. The nature of the toxic effects caused by boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents(rats)	NOAEL = 34/159 milligram/kilogram/day (mg/kg/day) Male/Female. LOAEL = 137/395 mg/kg/day M/F based on [M = increases in absolute and relative thyroid weights and increased incidence of thyroid hyperplasia as well as follicular epithelial hypertrophy; F = increases in absolute and relative thyroid weights.]

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents (mice)	NOAEL: 197/2,209 mg/kg/day (M/F) LOAEL: 788/2,209 mg/kg/day (M/F): M = increased liver weights and increased incidence of marked fatty change in the liver; F = not attained
870.3150	(90-day oral toxicity in nonrodents (dogs)	NOAEL: 7.6/8.1 mg/kg/day (M/F) LOAEL: 78.1/81.7 mg/kg/day (M/F): M = based on increased alkaline phosphatase activity and hepatic weights; F = increased alkaline phosphatase activity and hepatic weights.
870.3200	21/28-Day dermal toxicity (rats)	NOAEL = 1,000 mg/kg/day highest dose tested (HDT) LOAEL = >1,000 mg/kg/day
870.3700	Prenatal developmental in rodents (rats)	Maternal NOAEL = 1,000 mg/kg/day LOAEL = cannot be established Developmental NOAEL = 1,000 mg/kg/day LOAEL = cannot be established
870.3700	Prenatal developmental in nonrodents (rabbits)	Maternal NOAEL = 300 mg/kg/day LOAEL = 1,000 mg/kg/day based on abortions or early delivery. Developmental NOAEL = 300 mg/kg/day LOAEL = 1,000 mg/kg/day based on abortions or early delivery.
870.3800	Reproduction and fertility effects (rats)	Parental/Systemic NOAEL = 112.6/1180.8 mg/kg/day M/F Parental/Systemic LOAEL = 1165.0/>1180.8 mg/kg/day M/F based on decreased body weight and body weight gain (F_1) as well as hepatocyte degeneration F_0 and F_1) in males only. Offspring systemic NOAEL = 11.2/115.8 mg/kg/day (M/F) Offspring systemic LOAEL = 112.6/1180.8 (M/F) mg/kg/day based on decreased body weight for F_2 pups in males and females of both generations. Reproductive NOAEL = 1165.0/1180.8 mg/kg/day (M/F) Reproductive LOAEL = >1165.0/1180.8 mg/kg/day (M/F)
870.4100	Chronic toxicity rodents (rat)	NOAEL = 21.9/30.0 mg/kg/day (M/F) LOAEL = 110.0/150.3 mg/kg/day (M/F) based on M = thyroid toxicity (weights and microscopic changes); F - thyroid toxicity (weights and microscopic changes. Thyroid follicular cell adenomas: M - 0/20, 0/20, 2/20, 1/20; F = 0/20, 0/20, 1/20, 0/20.
870.4100	Chronic toxicity (dogs)	NOAEL = 21.8/22.1 mg/kg/day (M/F) LOAEL = 57.4/58.3 mg/kg/day (M/F) based on M = elevated ALP activities and elevated hepatic weights; F = no effects
870.4200	Carcinogenicity (rats)	NOAEL = 23.0/29.7 mg/kg/day (M/F) LOAEL = 116.1/155.6 mg/kg/day (M/F) based on M = increased incidence of thyroid follicular cell hyperplasia and hypertrophy; F = decrease in body weight gain and increased incidence of thyroid follicular cell hyperplasia and hypertrophy. Thyroid follicular cell adenomas: M = 0/50, 0/50, 1/50, 4/50; F = 0/50, 1/50, 0/50, 3/50.
870.4200	Carcinogenicity (mice)	NOAEL: 65/443 mg/kg/day (M/F) LOAEL: 331/1804 mg/kg/day (M/F): M = decreases in body weight and body weight gains; F = decreases in body weight and body weight gains. No evidence of carcinogenicity.
870.5100	Gene Mutation bacterial reverse mutation assay	Negative without and with S-9 activation up to limit dose of 5,000 μg/plate.
870.5300	*In vitro* mammalian cell forward gene mutation assay (CHO cells/ HGPRT locus)	Negative without and with S-9 activation up to limit of solubility of 25 μg/plate.
870.5375	*In vitro* mammalian cytogenetics assay in Chinese hamster V79 cells	Negative without and with S-9 activation up to 3500 μg/mL with precipitation showing at concentrations of 100 μg/mL and higher.
870.5395	Cytogenetics - mammalian erythrocyte micronucleus test in the mouse	Negative response up to 2,000 mg/kg.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5500	*In vitro* unscheduled DNA synthesis (primary rat hepatocytes)	Negative response up to 50 μg/mL. Cytotoxicity at 100 - 500 μg/mL.
870.6200	Acute neurotoxicity screening battery (rat)	NOAEL = 2,000/1,000 mg/kg/day (M/F) LOAEL = >2,000/2,000 mg/kg/day (M/F) based on F = piloerection
870.6200	Subchronic neurotoxicity screening battery (rat)	NOAEL = 1050.0/1272.5 mg/kg/day (M/F) LOAEL = >1050.0/1272.5 mg/kg/day (M/F)
870.6300	Developmental neurotoxicity (rat)	Maternal NOAEL = 1,442 mg/kg/day LOAEL = >1,442 mg/kg/day Offspring NOAEL = 14 mg/kg/day LOAEL = 147 mg/kg/day based on deceased body weights on PND 4 and decreased body weight gain on PNDs 1-4)
870.7485	Metabolism and pharmaco-kinetics (rat)	BAS 510 was readily absorbed and excreted following single oral 50 mg/kg; at single 500 mg/kg or 15 doses of 500 mg/kg, absorption was saturated . Excretion mainly by feces (80-98%). Biliary excretion 40-50% of fecal activity at 50 mg/kg, 10% at 500 mg/kg. Urine, about 16% at 50 mg/kg, 3-5% at 500 mg/kg. Absorption about 56% at 50 mg/kg and 13-17% at 500 mg/kg. Excretory patterns similar by gender or radiolabel position. Metabolites (hydroxylation and conjugation products) were consistent with Phase I oxidation reactions followed by Phase II conjugation with glucuronic acid or sulfate, or by conjugation of the parent with glutahione with cleavage to sulfate metabolites.
870.7600	Dermal penetration (rat)	Maximum % absorption: 0.01 mg/cm^2 = 10.93 (24 hour exposure, 24 hour sacrifice) 0.10 mg/cm^2 = 3.76 (24 hour exposure, 24 hour sacrifice) 1.00 mg/cm^2 - 1.48 (10 hour exposure, 72 hour sacrifice)]
	Special studies: Hepatic enzyme induction (rat)	1. Hypertrophy of zone III hepatocytes 2. >20% increase in liver weight 3. Increase in CYP450 activity 4. Slight to extensive microscopic SER proliferation 5. Not a peroxisome proliferator 6. Enzymes in CYP450 subfamily not induced 7. No notable microscopic increase in size or number of peroxisomes CONCLUSION: Inducer of total CYP450 activity
	Special Study: Hormone and enzyme induction (rat)	1. Slight (statistically significant) decrease in circulating T_3 and T_4 only in males 2. Increase in circulating TSH levels both sexes 3. Increase in all 3 liver microsomal glucuronyltransferases CONCLUSION: disruption of thyroid homoeostasis by decreasing circulation T3 and T4 and increasing TSH; likely the result of hepatic microsomal glucuronyltransferase induction
	Special Study: Reversibility study (dietary): 4-week administration followed by 4 weeks recovery or 13 weeks recovery (rat)	4 weeks dosing: at 2500 and 15000 ppm: increase in TSH (68% and 87%) ; increase in absolute and relative thyroid weights hypertrophy of thyroid follicular epithelial cells and diffuse follicular hyperplasia, increase in absolute and relative liver weights and centrilobular hypertrophy as well as liver portal fatty changes. 4 weeks dosing + 4 weeks recovery: no increases in TSH; increase in absolute and relative thyroid weights; thyroid hypertrophy and hyperplasia decreased to control values; all liver effects reversed to control. 4 weeks dosing + 13 weeks recovery: no increases in TSH; increase in absolute and relative thyroid weights; thyroid hypertrophy and hyperplasia decreased to control values; all liver effects reversed to control. CONCLUSION: induction of liver microsomal enzyme system resulting in increased glucuronidation of thyroxine, resulting in an increase in TSH secretion as a compensatory response of the physiological negative feedback system; increased TSH resulted in increased thyroid weight.

B. Toxicological Endpoints

The dose at which 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where

the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a point of departure is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for boscalid used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BOSCALID FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary	No appropriate endpoint identified	Not Applicable	Not Applicable
Chronic Dietary (All populations)	NOAEL= 21.8 UF = 100 Chronic RfD = 0.218 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/ FQPA SF = 0.218 mg/kg/day	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Incidental Oral (Short and intermediate term residential only)	NOAEL= 21.8 mg/kg/day	Residential LOC for MOE = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Dermal (All Durations)	Oral study NOAEL=21.8 mg/kg/day (dermal absorption rate = 15%)	Residential LOC for MOE = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Inhalation (All Durations)	Oral study NOAEL= 21.8 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Cancer (oral, dermal, inhalation)	Classification: Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential.		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. These are the first food uses and tolerances for residues of boscalid, in or on raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from boscalid in food as follows:

i. *Acute exposure*. Acute dietary 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. 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, including infants and children, or to the subpopulation females 13-50 years old. Therefore, there is no acute reference dose (aRfD) or acute population-adjusted dose (aPAD).

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption 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: Tolerance level residues were assumed for all commodities associated with PP 1F6313 with the exception of a few crops where levels higher than the tolerance were used. The latter were due to the lowering of some tolerances to harmonize with Canadian MRL's subsequent to the dietary risk assessment. Pome fruit and hops were also included from PP 2F6434 using the likely tolerance levels. One hundred percent crop treated was assumed for all commodities. Processing factors were either empirical or the default values in DEEM.

iii. *Cancer*. The Agency determined that boscalid produced suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential. This cancer classification 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. Consistent with this weak evidence of carcinogenic effects, the Agency concluded that a dose-response assessment for cancer (either linear low-dose extrapolation or margin of exposure calculation) was not needed.

iv. *Anticipated residue and percent crop treated (PCT) information*. The Agency used tolerance level residues and 100% crop treated for this risk analysis.

2. *Dietary exposure from drinking water*. This is a new chemical and 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.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to boscalid they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of boscalid for chronic exposures are estimated to be 25.6 ug/L for surface water and 0.571 ug/L for ground water. The Agency notes that for surface and groundwater assessments, the application rate for turf was used, which represents the highest seasonal application rate (2.1 lbs. active ingredient/acre/season). The highest single application rate associated with the use of the pesticide on fruiting vegetables, did not result in EEC values higher than those calculated for turf use since the proposed total seasonal application rate for fruiting vegetables is only 1.1 lb. active ingredient/acre/season.

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 being registered for use on the following residential non-dietary sites: The boscalid label with turf use 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 label does not indicate that the product is applied by licenced or commercial applicators, homeowners will not be applying the product to golf courses. Therefore, a risk assessment for residential handler exposure is not required. The risk assessment was conducted using the following residential exposure assumptions: The Agency uses the term post-application to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. There are two recreational scenarios associated with boscalid that could lead to exposures for adults and children: (i) Adults and youth golfing and (ii) adults and children picking their own fruit. These exposure durations are anticipated to be short term. 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/risk was not evaluated. Therefore, only the golfing scenario was evaluated with respect to non-occupational, non-dietary exposure. The dermal MOEs for adults golfing were 27,000-74,000. Although specific MOEs were not calculated for youths playing golf, the adult MOEs are considered representative since the body surface area to weight ratios for adolescents do not vary significantly from those for adults. The refined assessment is based on reliable data and is unlikely to underestimate exposure/risk.

4. *Cumulative exposure to 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.''

EPA does not have, at this time, available data to determine whether boscalid has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the 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 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. The Agency concluded that there are no residual uncertainties for pre- and post-natal 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 2–generation reproduction or the developmental neurotoxicity studies. Based on these data, the Agency concluded that there are no residual uncertainties for pre- and post-natal toxicity.

3. *Conclusion*. There is a complete toxicity data base for boscalid and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. There is no evidence of susceptibility following *in utero* exposure to rats and there is low concern and no residual uncertainties in the developmental toxicity study in rabbits, in the 2–generation reproduction study or in the developmental neurotoxicity study after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment. Based on these data and conclusions, EPA reduced the FQPA Safety Factor to 1X.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

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. Therefore, there is no acute reference dose (aRfD) or acute population-adjusted dose (aPAD) for the general population or females 13-50 years old. No acute risk is expected from exposure to boscalid.

2. *Chronic risk*. The chronic aggregate risk assessment takes into account average exposures estimates from dietary consumption of boscalid (food and drinking water) and residential uses. Since the exposure from turf grass (golf course) activities are considered short term, the chronic aggregate included food and drinking water only. The calculated chronic DWLOCs for chronic exposure to boscalid in drinking water range from 1,400 to 7,000 µg/L (ppb).). The chronic aggregate risk associated with the proposed use of boscalid does not exceed the Agency's level of concern for the general U.S. population or any population subgroups. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO BOSCALID

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.218	8	25.6	0.571	7,000

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO BOSCALID—Continued

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
All Infants (< 1 year old)	0.218	24	25.6	0.571	1,700
Children 1-2 years old	0.218	35	25.6	0.571	1,400
Females 13-49 years old	0.218	5	25.6	0.571	6,200
Adults 50+ years old	0.218	6	25.6	0.571	7,200

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).

Boscalid is proposed for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for boscalid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in an aggregate MOE of 1,200 for the general population. The short-term aggregate risk assessment takes into account average exposures estimates from dietary consumption of boscalid (food and drinking water) and residential uses. Postapplication exposures from the proposed use on golf course is considered a short term activity and applies to adults and youth. The Agency concluded that exposure from turf grass is needed to be included in the aggregate assessment. Table 4 summarizes the results. For the general population the MOE from food and residential exposure was 1,200. This MOE is also representative of the risk for youth playing golf for the reasons stated in Unit III.C.3. and the dietary exposure for youth (13-19 years old) being less than the general population. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, a short-term DWLOC was calculated and compared to the EECs for chronic exposure of boscalid in ground and surface water. The calculated short term DWLOC is 6,000 ppb. After calculating the DWLOC and comparing it to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO BOSCALID

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
General population	1,200	100	25.60	0.571	6,000

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). Boscalid is not registered for use on any sites that would result in intermediate-term residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which does not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. The Agency has classified boscalid as, ''suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential,'' and, therefore, the quantification of human cancer risk is not recommended. See Unit III.C.iii of this document for additional details explaining why a cancer risk assessment was not required.

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

Analytical Enforcement Method for Plants. (Method D0008; MRID 45405028). This method determines residues of boscalid. Residues are extracted using an aqueous organic solvent mixture followed by liquid/liquid partitioning and column clean-up. Quantitation is by gas chromatography/mass spectrometry (GC/MS) using selected ion monitoring. The reported limit of quantitation (LOQ) is 0.05 ppm for residues of boscalid in plant matrices.

Analytical Enforcement Method for Livestock. (Method DFG S19; MRID 45405103). This method determines residues of boscalid and two metabolites 2-chloro-N-(4'-chloro-5-hydroxy-biphenyl-2-yl)nicotinamide (M510F01) and glucuronic acid conjugate of 2-chloro-N-4'-chloro-5-hydroxy-biphenyl-2-yl)nicotinamide (M510F02)] in or on the following food commodities (as 2-chloro-N-(4'-chloro-5-hydroxy-biphenyl-2-yl)nicotinamide). Residues are extracted with methanol. The extract is treated with enzymes to release M510F02 to free M510F01. Residues are isolated by liquid/liquid partition followed by column chromatography. Total M510F01 is acetylated followed by a column clean-up. Parent and acetylated M510F01 are quantitated by GC/ECD (electron capture). The reported LOQ for each analyte is 0.01 ppm in milk and 0.025 ppm in other animal matrices.

Adequate enforcement methodology (GC/MS and GC/ECD) 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

Boscalid is a new fungicide. There are currently no pending or established Codex maximum residue limits (MRLs) for boscalid, and no established Canadian or Mexican MRLs either. The US EPA and PMRA/Canada jointly reviewed this subject petition (1F6313), and the forthcoming tolerances were harmonized to the extent possible with respect to the residues of concern and tolerance levels.

C. Conditions

Any conditions of registration will be specified in the Notice of Registration for the technical grade boscalid.

V. Comments

The Agency received the following comment. The Agency's response follows.

Comment. There should be zero tolerance for ths chemical on food. We do not need more chemicals added to our food. We already have far too many approved by EPA and FDA. I say if there is anything over zero effect from this toxic, that the toxic should be denied use in the USA.

Response. The one comment received in response to the Notice of Filing contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to boscalid, including all anticipated dietary exposure and all other exposures for which there is reliable information. General opposition to pesticides in food is not a sufficient reason to deny a tolerance petition.

VI. Conclusion

Therefore, tolerances are established for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl), in or on vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip at 0.7 ppm; vegetable, tuberous and corm, subgroup 1C at 0.05 ppm; vegetable, bulb, group 3 at 3.0 ppm; lettuce, head at 6.5 ppm; lettuce, leaf at 11.0 ppm; vegetable, Brassica leafy, head and stem, subgroup 5A at 3.0 ppm; vegetable, Brassica leafy, leafy greens, subgroup 5B at 18.0 ppm; vegetable, legume, edible-podded, subgroup 6A, at 1.6 ppm; vegetable, legume, succulent shelled pea and bean, subgroup 6B, except cowpea; at 0.6 ppm; vegetable, legume, dried shell pea and bean (except soybean), subgroup 6C, except cowpea, field pea, and grain lupin at 2.5 ppm; vegetable, fruiting, group 8 at 1.2 ppm; vegetable, cucurbit, group 9, except cucumber at 1.6 ppm; cucumber at 0.20 ppm; fruit, stone, group 12 at 1.7 ppm; berries, group 13 at 3.5 ppm; nut, tree, group 14 at 0.70 ppm; almond, hulls at 3.0 ppm; pistachio at 0.70 ppm; grape at 3.5 ppm; grape, raisin at 8.5 ppm; strawberry at 1.2 ppm; peanut at 0.05 ppm; peanut, meal at 0.15 ppm; peanut, refined oil at 0.15 ppm; canola, seed at 3.5 ppm; canola, refined oil at 5.0 ppm; sunflower, seed at 0.60 ppm; peppermint, tops at 30.0 ppm and spearmint, tops at 30.0 ppm.

Tolerances are established for indirect or inadvertent (crop rotation) residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl), in or on beet, garden, roots at 1.0 ppm; radish, roots, at 1.0 ppm; turnip, roots at 1.0 ppm; beet, sugar, roots at 1.0 ppm; vegetable, root and tuber, leaves, group 2 at 1.0 ppm; vegetable, leafy, group 4, except lettuce at 1.0 ppm; vegetable, legume, foliage, group 7, forage at 1.5 ppm; vegetable, legume, foliage, group 7, hay at 2.0 ppm; vegetable, legume, foliage, group 7, vines at 0.05 ppm; grain, cereal, group 15 at 0.20 ppm; rice, hulls at 0.50 ppm; grain, cereal , forage, fodder, and straw, group 16, fodder at 1.5 ppm; grain, cereal , forage, fodder, and straw, group 16, forage at 2.0 ppm; grain, cereal , forage, fodder, and straw, group 16, straw at 3.0 ppm; grass, forage, fodder, and hay, group 17, forage at 2.0 ppm; grass, forage, fodder, and hay, group 17, hay at 8.0 ppm; grass, forage, fodder, and hay, group 17, straw at 0.30 ppm; grass, forage, fodder, and hay, group 17, seed screenings at 0.20 ppm; animal feed, nongrass, group 18, forage at 1.0 ppm; animal feed, nongrass, group 18, hay at 2.0 ppm; animal feed, nongrass, group 18, seed at 0.05 ppm; cotton, undelinted seed at 0.05 ppm; cotton, gin byproducts at 0.30 ppm; soybean, seed, 0.10 ppm; soybean, hulls at 0.20 ppm; cowpea, seed at 0.1 ppm; lupin, grain, grain at 0.1 ppm; pea, field, seed at 0.1 ppm and flax seed at 3.5 ppm.

Tolerances are established for the combined residues of the fungicide 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) and metabolites M510F01 2-chloro-N-(4'-chloro-5-hydroxy-biphenyl-2-yl) nicotinamide and M510F02 glucuronic acid conjugate of M510F01 in or on milk at 0.10 ppm; cattle, meat at 0.10 ppm; cattle, fat at 0.30 ppm; cattle, meat byproducts at 0.35 ppm; egg at 0.02 ppm; poultry, meat at 0.05 ppm; poultry, fat at 0.05 ppm; poultry, meat byproducts at 0.10 ppm; goat, meat at 0.10 ppm; goat, fat at 0.30 ppm; goat, meat byproducts at 0.35 ppm; hog, meat at 0.05 ppm; hog, fat at 0.10 ppm; hog, meat byproducts at 0.10 ppm; horse, meat at 0.10 ppm; horse, fat at 0.30 ppm; horse, meat byproducts at 0.35 ppm; sheep, meat at 0.10 ppm; sheep, fat at 0.30 ppm and sheep, meat byproducts at 0.35 ppm.

VII. Objections and Hearing Requests

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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0246 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 September 29, 2003.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C),

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall # 2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0246, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the 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 the 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 the 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.

IX. 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 record keeping requirements.

Dated: July 21, 2003.

James Jones,

Director, 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), 346(a) and 371.

■ 2. Section 180.589 is added to read as follows:

§ 180.589 Boscalid; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide 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
Almond hulls	3.0
Berries, group 13	3.5
Canola, refined oil	5.0
Canola, seed	3.5
Cucumber	0.20
Fruit, stone, group 12	1.7
Grape	3.5
Grape, raisin	8.5
Lettuce, head	6.5
Lettuce, leaf	11.0
Nut, tree, group 14	0.70
Peanut	0.05
Peanut, meal	0.15
Peanut, refined oil	0.15
Peppermint, tops	30.0
Pistachio	0.70
Spearmint, tops	30.0
Strawberry	1.2
Sunflower, seed	0.60
Vegetable, Brassica leafy, head and stem, subgroup 5A	3.0
Vegetable, Brassica leafy, leafy greens, subgroup 5B	18.0
Vegetable, bulb, group 3	3.0
Vegetable, cucurbit, group 9, except cucumber	1.6
Vegetable, fruiting, group 8	1.2
Vegetable, legume, dried shell pea and bean (except soybean), subgroup 6C, except cowpea, field pea, and grain lupin	2.5
Vegetable, legume, edible podded, subgroup 6A	1.6
Vegetable, legume, succulent shelled pea and bean, subgroup 6B, except cowpea	0.6
Vegetable, root, subgroup 1A , except sugar beet, garden beet, radish, and turnip	0.7
Vegetable, tuberous and corm, subgroup 1C	0.05

(2) Tolerances are established 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 the following food commodities:

Commodity	Parts per million
Cattle, fat	0.30
Cattle, meat	0.10
Cattle, meat byproducts	0.35
Egg	0.02
Goat, fat	0.30
Goat, meat	0.10
Goat, meat, byproducts	0.35
Hog, fat	0.10
Hog, meat	0.05
Hog, meat byproducts	0.10
Horse, fat	0.30
Horse, meat	0.10
Horse, meat byproducts	0.35
Milk	0.10
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat, byproduct	0.10
Sheep, fat	0.30
Sheep, meat	0.10
Sheep, meat byproducts	0.35

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registration.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of the fungicide boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) in or on the following raw agricultural commodities when present therein as a result of application of boscalid to the growing crops in paragraph (a)(1) of this section:

Commodity	Parts per million
Animal feed, nongrass, group 18, forage	1.0
Animal feed, nongrass, group 18, hay	2.0
Animal feed, nongrass, group 18, seed	0.05
Beet, garden, roots	1.0
Beet, sugar, roots	1.0
Cotton, gin byproducts	0.30
Cotton, undelinted seed	0.05
Cowpea, seed	0.1
Flax seed	3.5
Grain, cereal, forage, fodder and straw, group 16, fodder	1.5
Grain, cereal, forage, fodder and straw, group 16, forage	2.0
Grain, cereal, forage, fodder and straw, group 16, straw	3.0
Grain, cereal, group 15	0.20
Grass, forage, fodder, and hay, group 17, forage	2.0
Grass, forage, fodder, and hay, group 17, hay	8.0
Grass, forage, fodder, and hay, group 17, seed screenings	0.20
Grass, forage, fodder, and hay, group 17, straw	0.30
Lupin, grain, grain	0.1
Pea, field, seed	0.1
Radish, roots	1.0
Rice, hulls	0.50
Soybean, hulls	0.20
Soybean, seed	0.10
Turnip, roots	1.0
Vegetable, leafy, group 4, except lettuce	1.0
Vegetable, legume, foliage, group 7, forage	1.5
Vegetable, legume, foliage, group 7, hay	2.0
Vegetable, legume, foliage, group 7, vines	0.05
Vegetable, root and tuber, leaves, group 2	1.0

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