Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The costs to a foreign facility of hiring a U.S. agent;

b. The number of foreign facilities that have hired a U.S. agent or negotiated additional duties from someone with whom they have an existing relationship, in response to the IFR, instead of relying on an existing relationship with a person who qualifies as a U.S. agent;

c. The number of foreign facilities that have ceased exporting to the United States because they have decided not to hire/retain a U.S. agent for registration purposes;

d. The distribution of costs between submitting registrations and other services offered by the U.S. agent; and

e. The assumptions underlying FDA's estimates of the costs of hiring and retaining a U.S. agent.

2. The effects on domestic small businesses, if any, if some foreign facilities cease exporting to the United States due to the U.S. agent requirement for registration. Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The number of domestic small businesses that have been adversely affected by trading partners that have ceased exporting to the United States due to the U.S. agent requirement for foreign facility registration; and

b. The costs incurred by these domestic small businesses due to the loss of these trading partners.

To be timely, interested persons must submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the above issues as indicated in the **DATES** section of this document. Two copies of any comments are to be submitted by commenting entities; individuals may submit one copy. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

As noted, the IFR was effective on December 12, 2003. The agency will address comments on the identified set of issues that are received during this reopened comment period and were received during the previous comment period that closed on December 24, 2003, and will confirm or amend the IFR in a final rule. The agency, however, will not address any comments that have been previously considered during this rulemaking.

Dated: March 24, 2004.

Lester M. Crawford,

Acting Commissioner for Food and Drugs.

Dated: April 6, 2004.

Robert C. Bonner,

Commissioner, Customs and Border Protection.

[FR Doc. 04–8516 Filed 4–9–04; 4:51 pm]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0083; FRL–7351–9]

Thifensulfuron-methyl; Withdrawal of Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Because EPA received relevant adverse comment, the Agency is withdrawing the direct final rule for the reinstatement of corn tolerances for the herbicide thifensulfuron-methyl. EPA published the direct final rule on February 13, 2004 which would have reinstated corn tolerances for the herbicide thifensulfuron-methyl that were previously established but inadvertently removed shortly thereafter. EPA stated in that direct final rule that if relevant adverse comment were received by April 13, 2004, the Agency would publish a timely withdrawal in the **Federal Register**. EPA subsequently received relevant adverse comment on that direct final rule. EPA will therefore publish a notice of proposed rulemaking in a future edition of the **Federal Register**. The Agency will address the comments on the direct final rule as part of that proposed rulemaking.

DATES: As of April 14, 2004, EPA withdraws the direct final rule published at 69 FR 7161, on February 13, 2004.

FOR FURTHER INFORMATION CONTACT: Joseph Nevola, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–8037; e-mail address:*nevola.joseph@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA received a relevant adverse comment during the comment period for the February 13, 2004 (69 FR 7161) (FRL–7338–6) direct final rule in which the Agency stated that it would reinstate corn tolerances for residues of the herbicide thifensulfuron-methyl that were previously established by rulemaking in the **Federal Register** and that were inadvertently removed from 40 CFR 180.439. Because of a relevant adverse comment, EPA is withdrawing the direct final rule so that it will not take effect. EPA will publish a notice of proposed rulemaking in a future issue of the **Federal Register** and address the comments on the direct final rule as part of that notice of proposed rulemaking.

Currently, there are active products registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) which list corn as a use site for thifensulfuron-methyl application. These registrations have existed since 1994 with associated tolerances established in May 1994. In the direct final rule of February 13, 2004 (69 FR 7161), EPA stated that the deletion of the corn tolerances from the 40 CFR was both inadvertent and improper.

List of Subjects in 40 CFR Part 180

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

Dated: March 26, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Accordingly, the direct final rule for thifensulfuron-methyl published in the **Federal Register** of February, 13, 2004 at 69 FR 7161 is withdrawn.

[FR Doc. 04–8103 Filed 4–13–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0075; FRL–7353–1]

Boscalid; 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 residues of boscalid in or on pome fruit crop group, group 11 at 3.0 ppm, apple pomace, wet at 10.0 ppm, hops cones, dried at 35.0 ppm, soybean, vegetable at 2.0 ppm, soybean seed at 0.1 ppm, soybean hulls at 0.2 ppm and aspirated grain fractions at 3.0

ppm. BASF Corporation requested this tolerance 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 April 14, 2004. Objections and requests for hearings, identified by docket ID number OPP–2004–0075, must be received on or before June 14, 2004.

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 VI. 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, 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 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–2004–0075. 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.gpoaccess.gov/ecfr/*, 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 November 6, 2003 (68 FR 215) (FRL–7321–1), 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 petitions (PP 2F6434 and 3F6580) by BASF Corporation, P.O. Box 13528, Research Triangle Park, North Carolina 27708–2000. That notice included a summary of the petitions prepared by BASF Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.589 be amended by establishing a tolerance for residues of the fungicide boscalid in or on pome fruit crop group, group 11 at 3.0 ppm, apple pomace, wet at 20.0 ppm, hops cones, dried at 35.0 ppm, soybean, vegetable at 2.2 ppm, soybean seed at 0.1 ppm, soybean hulls at 0.2 ppm and soybean aspirated grain fractions at 2.5 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 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 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 a tolerance for residues of boscalid. EPA's assessment of exposures and risks associated with establishing the tolerance follows. This assessment involves adding tolerances for commodities of pome fruit crop group, group 11 at 3.0 ppm, apple pomace, wet at 10.0 ppm, hops cones, dried at 35.0 ppm, soybean, vegetable at 2.0 ppm,

soybean seed at 0.1 ppm, soybean hulls at 0.2 ppm and soybean aspirated grain fractions at 3.0 ppm.

A. Toxicological Profile

EPA previously 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 as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of July 30, 2003 (68 FR 44640) (FRL–7319–6). No new information which would change the toxicological profile has been submitted or reviewed since the analysis.

B. Toxicological Endpoints

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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: "Traditional uncertainty factors;'' the "special FQPA safety factor;'' and the "default FQPA safety factor.'' By the term "traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term "special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The "default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10× 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 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) for the residues of boscalid, in or on a variety of 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 the chronic dietary risk 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:

The chronic dietary exposure analysis was performed using two separate models: DEEM- FCID™ and Lifeline™. The analysis was based on tolerance-level residues (in some cases modified by DEEM™ (Version 7.81) default processing factors), and assume 100% crop treated. In both cases, the risk estimates are well below the Agency's level of concern for the general U.S. population and all population subgroups. The results of the DEEM-FCID™ and Lifeline™ analyses are comparable. The most highly exposed population subgroup from DEEM™ is children 1–2 years, which has an exposure estimate of 0.057 mg/kg/day, and utilizes 26% of the cPAD. The most highly exposed population subgroup from Lifeline™ is also children 1–2 years, which has an exposure estimate of 0.053 mg/kg/day, and utilizes 24% of the cPAD.

TABLE 1.—SUMMARY OF DIETARY EXPOSURE AND RISK FOR BOSCALID

Population Subgroup	Acute Analysis	DEEM: Chronic Analysis		Lifeline: Chronic Analysis	
		Dietary Exposure (mg/kg/day)	% cPAD	Mean Exposure (mg/kg/day)	% cPAD
General U.S. Population	Not applicable: No acute dietary endpoint	0.014597	6.7	0.01378	6.3
All Infants (<1 year old)	Not applicable: No acute dietary endpoint	0.03509	16	0.03421	16
Children 1–2 years old	Not applicable: No acute dietary endpoint	0.056809	26	0.0525	24
Children 3–5 years old	Not applicable: No acute dietary endpoint	0.039112	18	0.03983	18
Children 6–12 years old	Not applicable: No acute dietary endpoint	0.019162	8.8	0.01806	8.3
Youth 13–19 years old	Not applicable: No acute dietary endpoint	0.01046	4.8	0.00975	4.5
Adults 20–49 years old	Not applicable: No acute dietary endpoint	0.010351	4.7	0.01094	5
Adults 50+ years old	Not applicable: No acute dietary endpoint	0.010935	5	0.01121	5.1
Females 13–49 years old	Not applicable: No acute dietary endpoint	0.010349	4.7	0.01191	5.5

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 because boscalid was 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.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/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 ground water. 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. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 I.

Based on the FIRST and SCI-GROW models, the EECs of boscalid for acute and chronic exposures for surface water are estimated to be 87.53 parts per billion (ppb) and 25.77 ppb, respectively, and the ground water EEC is 0.63 ppb. Since the completion of the previous risk assessment for boscalid, the aerobic soil metabolism half lives used as input parameters for the FIRST and SCI-GROW models have been revised.

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).

No new residental uses of boscalid are currently being registered that would increase non-dietary exposure. A non-occupational dermal post-application exposure/risk assessment for individuals golfing and harvesting fruit at "U-pick'' farms and orchards was conducted in the previous occupational and residential exposure (ORE) assessment.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information'' concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity.''

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 OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site 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 10-fold 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 an 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.* A complete discussion of the prenatal/postnatal sensitivity study was recently discussed in our final rule dated July 30, 2003 (68 FR 44640) (FRL–7319–6). No new information has been received to change this information. The Agency does restate the basic conclusion from that analysis. 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 2-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. The submitted field trials performed on hops, pome fruit, and soybeans are adequate to support the recommended tolerances: Hops cones, dried (35 ppm), pome fruit (3.0 ppm), apple pomace, wet (10 ppm), soybean vegetable (2.0 ppm), soybean seed (0.1 ppm), soybean hulls (0.2 ppm), soybean aspirated grain fractions (3.0 ppm). 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 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 EPA's 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 ground water 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 dietary exposure analysis was based on tolerance-level residues (in some cases modified by DEEM (Version 7.81) default processing factors), and assume 100% crop treated. Even with these highly conservative assumptions, the risk estimates are well below the Agency's level of concern. The most highly exposed population subgroup from DEEM™ is children 1–2 years, which has an exposure estimate of 0.057 mg/kg/day, and utilizes 26% of the cPAD. The most highly exposed population subgroup from Lifeline™ is also children 1–2 years, which has an exposure estimate of 0.053 mg/kg/day, and utilizes 24% of the cPAD.

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BOSCALID

Senario/Population Subgroup	cPAD mg/kg/day	Chronic Food Exposure, mg/kg/day	Maximum Chronic Water Exposure[1], mg/kg/day	Ground Water EDWC[2], (ppb)	Surface Water EDWC[2], (ppb)	Chronic DWLOC[3] (ppb)
General U.S. Population	0.218	0.014597	0.2034	0.63	26	7,100
All infants (< 1 year old)	0.218	0.03509	0.18291	0.63	26	1,800
Children 1–2 years old	0.218	0.056809	0.16119	0.63	26	1,600
Females 13–49 years old	0.218	0.010349	0.20765	0.63	26	6,200

[1]Maximum chronic water exposure (mg/kg/day) = cPAD (mg/kg/day) - chronic food exposure from dietary exposure analysis (mg/kg/day).
[2]EDWCs from EFED studies.
[3]Chronic DWLOCs were calculated as follows:
Chronic DWLOC(μg/L) = [maximum chronic water exposure (mg/kg/day) x body weight (kg)]/[water consumption (L) x 10^{-3} mg/μg]

3. *Short-term risk.* The short-term aggregate risk assessment takes into account average exposure estimates from dietary consumption of boscalid (food and drinking water) and non-occupational uses (golf courses). Postapplication exposures from the proposed use on golf courses is considered short- term, and applies to adults and youth. Therefore, a short-term aggregate risk assessment was conducted. Since all endpoints are from the same study, exposures from different routes can be aggregated. Table 3 summarizes the results. The MOE from food and non-occupational uses is 1400, and the calculated short-term DWLOC is 6,100 ppb. Compared to the surface and ground water EDWCs, the DWLOCs are considerably greater. Therefore, short-term aggregate risk does not exceed HED=s level of concern.

The MOE and DWLOC are considered to be representative for youth because youth 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.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO BOSCALID

Population	Short-Term Scenario									
	NOAEL mg/kg/day	Target MOE[1]	Max Exposure[2] mg/kg/day	Average Food Exposure mg/kg/day	Residential Exposure[3] mg/kg/day	Aggregate MOE[4] (food and residential)	Max Water Exposure[5] mg/kg/day	Ground Water EDWC[6](units)	Surface Water EDWC[6] (units)	Short-Term DWLOC[7,8] (μg/L)
U.S.	21.8	100	0.218	0.014597	0.0008	1400	0.2026	0.63	25.77	6,100

[1]The target MOE for dermal is 100.
[2]Maximum Exposure (mg/kg/day) = NOAEL/Target MOE
[3]Residential Exposure = Dermal exposure from golf course only
[4]Aggregate MOE = [NOAEL) (Avg Food Exposure + Residential Exposure)]
[5]Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure)
[6]The crop producing the highest level was used.
[7] DWLOC(Fg/L) = [maximum water exposure (mg/kg/day) x body weight (kg)]/ [water consumption (L) x 10^{-3} mg/μg]
[8]Adult female body weight was used, which covers adult male risk. The dietary exposure for the U. S. population is higher than that of groups having residential (golf) exposure (i.e., adults, youth 13–19).

4. *Aggregate cancer risk for U.S. population*. For the reason stated above, EPA does not expect boscalid to pose a cancer risk.

5. *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 (example—gas chromotography) 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 relatively new fungicide. There are currently no pending or established Codex maximum residue limits (MRLs) for boscalid. There are also no Mexican MRLs. The previous risk assessment was performed as a joint review with PMRA/Canada. The tolerances were harmonized with respect to the residue of concern and tolerance level.

V. Conclusion

Therefore, the tolerances are established for residues of boscalid in or on apple pomace, aspirated grain fractions at 3.0 ppm, wet at 10.0 ppm, hops cones, dried at 35.0 ppm, pome fruit crop group, group 11 at 3.0 ppm, soybean hulls at 0.2 ppm, soybean seed at 0.1 ppm, and soybean, vegetable at 2.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of 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 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–2004–0075 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 June 14, 2004.

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 VI.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–2004–0075, 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).

VII. 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.

VIII. 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: March 31, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.589 is amended by alphabetically adding commodities to the table in paragraph (a)(1) to read as follows:

§ 180.589 Boscalid; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
* * *	* *
Apple, wet, pomace	10
Aspirated grain fractions	3.0
* * *	* *
Fruit, pome, crop group, group 11	3.0
* * *	* *
Hops, cones, dried	35
* * *	* *
Soybean, hulls	0.2
Soybean, seed	0.1
Soybean, vegetable	2.0
* * *	* *

* * * * *

■ 3. Section 180.589 paragraph (d) is amended by removing tolerances for "Soybean, hulls,'' and "Soybean, seed'' from the table.

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CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

45 CFR Part 2552

RIN 3045–AA29

Foster Grandparent Program; Amendments

AGENCY: Corporation for National and Community Service.