Subpart C—Section 107 Attainment Status Designations

■ 2. In § 81.304 the table for Arkansas—Ozone (8-hour Standard) is amended by revising the entry for Memphis, TN–AR and footnote 2 to read as follows:

§ 81.304 Arkansas.

* * * * *

ARKANSAS—OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
Memphis, TN–AR: (AQCR 018 Metropolitan Memphis Interstate) Crittenden County.	.....	Nonattainment	([2])	Subpart 2/Moderate.
* * *	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.
[2] April 28, 2008.

* * * * *

■ 3. In § 81.343 the table for Tennessee—Ozone (8-hour Standard) is amended by removing footnote 3 and revising the entry for ''Memphis, TN–AR'' to read as follows:

§ 81.343 Tennessee.

* * * * *

TENNESSEE—OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
* * *	*	*	*	*
Memphis, TN–AR: Shelby County	.....	Nonattainment	March 28, 2008	Subpart 2/Moderate.
* * *	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.

* * * * *

[FR Doc. E8–6287 Filed 3–27–08; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0145; FRL–8354–4]

Boscalid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of boscalid in or on caneberry subgroup 13A at 6.0 parts per million (ppm); bushberry subgroup 13B at 13 ppm; cotton, undelinted seed at 1.0 ppm; cotton, gin by-products at 55 ppm; avocado at 1.5 ppm; sapote, black at 1.5 ppm; canistel at 1.5 ppm; sapote, mamey at 1.5 ppm; mango at 1.5 ppm; papaya at 1.5 ppm; sapodilla at 1.5 ppm; and star apple at 1.5 ppm. It revokes the existing berries, group 13 tolerance at 3.5 ppm because the two new caneberry and bushberry tolerances cover all commodities in the berries, group 13. Tolerances are being increased for cucumber from 0.20 ppm to 0.5 ppm, and vegetable, root, subgroup 1A, except sugarbeet, garden beet, radish, and turnip from 0.7 ppm to 1.0 ppm. BASF, Inc requested these tolerance actions under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this action establishes a time-limited tolerance for residues of boscalid in or on Endive, Belgian, in response to the approval of a crisis exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing the post harvest use of the fungicide on Endive, Belgian to control the fungal pathogen, scelerotinia sclerotiorum. This regulation establishes a maximum permissible level of residues of boscalid in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2009.

DATES: This regulation is effective March 28, 2008. Objections and requests for hearings must be received on or before May 27, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0145. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–

4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Bryant Crowe, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0025; e-mail address: *crowe.bryant@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2005–0145 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before May 27, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2005–0145, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of February 15, 2006 (71 FR 7951) (FRL–7759–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F6986) by BASF, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.589 be amended by increasing the tolerance for residues of the fungicide boscalid in or on berries, crop group 13 from 3.5 to 8.0 ppm; and increasing the tolerance for strawberries from 1.2 ppm to 4.0 ppm. That notice referenced a summary of the petition prepared by BASF, the registrant, which is available to the public in the docket, *http://www.regulations.gov*.

On April 4, 2007, in the **Federal Register** (72 FR 16352) (FRL–8119–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E7164) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, proposes to establish a tolerance for residues of the fungicide boscalid in or on food commodities avocado at 1.5 ppm; sapote, black at 1.5 ppm; canistel at 1.5 ppm; sapote, mamey at 1.5 ppm; mango at 1.5 ppm; papaya at 1.5 ppm; sapodilla at 1.5 ppm; star apple at 1.5 ppm; and herbs, fresh, subgroup 19A at 60.0 ppm. Fresh herbs, subgroup 19A, tolerances were subsequently withdrawn from this petition, on February 6, 2008, by IR-4, in accordance with 40 CFR 180.8. The docket ID number EPA–HQ–OPP–2007–0115, identifies this petition.

On June 27, 2007, EPA issued a notice pertaining to boscalid announcing the filing of a pesticide petition (PP 7F7169), (72 FR) (FRL–8133–4), by BASF, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709. The petition, identified by the docket ID number EPA–HQ–OPP–2007–0377, requested that 40 CFR 180.589 amended by increasing the tolerance for residues of the fungicide boscalid in or on cotton, undelinted seed at 1.0 ppm and cotton, gin byproducts at 55.0 ppm. In the **Federal Register** of February 13, 2008 (73 FR 7951) (FRL–7759–3), EPA issued a notice pertaining to boscalid announcing the filing of a pesticide petition (PP 5F6986) by BASF. The petition requested that 40 CFR 180.589 be amended by increasing the tolerance for residues of the fungicide boscalid in or on caneberry, crop group 13A at 6.0 ppm; bushberry, crop group 13B at 10.0 ppm; cucumber at 0.5 ppm; and vegetable, root, subgroup 1A, except sugar beet, garden beet, radish and turnip at 1.0 ppm.

Each petition's notice referenced a summary of the petition prepared by the registrant BASF, which is available to the public in the docket, *http://www.regulations.gov*. For the foregoing petitions, there were no comments in response to their notice of filing

Based upon review of the data supporting the petition, an increased strawberry tolerance to 4.5 ppm is not needed because EPA previously increased the strawberry tolerance to 4.5 ppm via the rule published May 3, 2006 (71 FR 25956) (FRL–8064–4). Furthermore, whereas the registrant requested the tolerance for the entire berry group 13 be increased from 3.5 ppm to 8.0 ppm, the Agency has established a separate tolerance for each of the two berry group 13 sub groups. Thus, where there was one tolerance for the entire group, there are now two separate tolerances covering all crops in the entire berry crop group 13. Thus, the existing berries, group 13 tolerance is being revoked because it is not needed.

BASF submitted field trial data on cucumbers, mustard greens, and sunflower. These field trials were required as a condition for the registration of boscalid on these crops. BASF has also submitted supplemental field trials on fruiting vegetables, spearmint and peppermint, radishes, stone fruits, and grapes, which were conducted to support the use of boscalid on these crops in Canada. Review of these new data is the basis for the need to increase the existing tolerances in or on cucumber from 0.2 to 0.5 ppm, and vegetable, root, subgroup 1A, except sugarbeet, garden beet, radish, and turnip from 0.7 to 1.0 ppm.

EPA is also establishing a time-limited tolerance for residues of the fungicide boscalid in or on Endive, Belgian at 16 ppm. This tolerance expires and is revoked on December 31, 2009. The Agency is establishing this time-limited tolerance in response to a crisis exemption request under FIFRA section 18 on behalf of the California Environmental Protection Agency, Department of Pesticide Regulation for emergency use of boscalid as a post harvest treatment on chicory roots to control fungal growth of scelerotinia sclerotiorum.

According to the applicant, the dormant chicory roots are taken out of cold storage and propagated in sheds within a controlled environment to stimulate bud development. These edible buds are known as belgian endive, and are marketed in grocery stores throughout the year. Based on information provided in the submission, an emergency situation exists because the pathogen, scelerotinia sclerotiorum, resides in field soils and can grow on the chicory root during cold storage, which makes the produce unmarketable. Vinclozolin had been registered for control of this pest until it was cancelled in 2001. Existing stocks of vinclozolin were used until 2003, and there are currently no other fungicides registered for the post harvest treatment of chicory root to control fungal growth. Further, the State claims that good agricultural practices are not sufficient to control this fungal pathogen.

As part of its assessment of the emergency exemption request, EPA assessed the potential risks presented by the residues of boscalid in or on endive, belgian, as discussed below. In doing so, EPA considered the safety standard in section 408 (b) (2) of the FFDCA, and EPA decided that the necessary time-limited tolerance under section 408 (l) (6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address the urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this time-limited tolerance without notice and opportunity for public comment as provided in section 408 (l) (6) of the FFDCA. Although, this time-limited tolerance expires and is revoked on December 31, 2009, under section 408 (l) (5) of the FFDCA, residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on endive, belgian after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data, or other relevant information on this pesticide indicates that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether boscalid meets EPA's registration requirements for use on endive, belgian or whether a permanent tolerance for this use would be appropriate. Under this circumstance, EPA does not believe that the time-limited tolerance serves as a basis for registration of boscalid by a State for special local needs under FIFRA section 24(c). Nor does the time-limited tolerance serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b) (2) (D) and the factors specified in FFDCA section 408(b) (2) (D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of boscalid on caneberry subgroup 13A, and bushberry subgroup 13B, respectively at 6.0 and 13 ppm; cotton, undelinted seed at 1.0 ppm; cotton, gin byproducts at 55 ppm; avocado at 1.5 ppm; sapote, black at 1.5 ppm; canistel at 1.5 ppm; sapote, mamey at 1.5 ppm; mango at 1.5 ppm; papaya at 1.5 ppm; sapodilla at 1.5 ppm; star apple at 1.5 ppm; cucumber at 0.5 ppm; and vegetable, root, subgroup 1A, except sugar beet, garden beet, radish and turnip at 1.0 ppm, as well as the time-limited tolerance for residues of boscalid in or on endive, belgian at 16 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Animal studies indicate that repeat dosing with boscalid results in effects in the liver and/or thyroid in various species. Mechanistic studies indicated

that the thyroid effects were derivative of enzymatic effects on the liver. The boscalid database shows no effects that were attributable to a single dose, and thus boscalid is deemed not to pose an acute risk. Testing involving *in utero* and/or post-natal exposure of animals shows no developmental or reproductive effects; however, this testing resulted in some findings of qualitative or quantitative sensitivity with regard to body weight effects in the young.

The Agency determined that boscalid shows suggestive evidence of carcinogenicity. This finding is 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 is 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 quantitative risk and exposure assessment for cancer (either linear low-dose extrapolation or margin of exposure calculation) was not appropriate.

Specific information on the studies received and the nature of the adverse effects caused by boscalid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov.* The referenced documents are available in the docket established by this action, which are described under **ADDRESSES**, and are identified as follows:

•*Boscalid:* Human Health Risk Assessment for Section 3 Tolerance on Endive, an Amendment to the Tolerances for Strawberries and Berries, Crop Group 13, and an Increase in Tolerances in/on Cucumber and Vegetable, Root, Subgroup 1A, except Sugar Beet, Garden Beet, Radish, and Turnip, dated 7-10-07.

• *Boscalid:* Addendum to the July 10, 2007 Human Risk Assessment to Support a Section 3 Use on Endive, an Amendment to the Tolerances for Strawberries and Berries, Crop Group 13, and an Increase in Tolerances in/on Cucumber and Vegetable, Root, Subgroup 1A, except Sugar Beet, Garden Beet, Radish, and Turnip.PC Code: 128008, Petition Nos: 5E7013, 5F6986, DP Barcode: 34857, dated 2-13-08.

• *Boscalid:* Human Health Risk Assessment to Support Proposed New Uses on Fresh Herbs (Herbs Subgroup 19A), Avocado, Black Sapote, Canistel, Mamey Sapote, Mango, Papaya, Sapodilla, Star Apple and Cotton. PC Code: 128008; Petition Nos: 6E7164, 7F7169; DP Barcodes: 336182, 337369, dated 2-13-08.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see:

http://www.epa.gov/oppfead1/trac/science

http://www.epa.gov/pesticides/factsheets/riskassess.htm

http://www.epa.gov/pesticides/trac/science/ aggregate.pdf

A summary of the toxicological endpoints for boscalid used for human risk assessment is discussed in Unit III.B of the final boscalid 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.* In evaluating dietary exposure to boscalid tolerances in (40 CFR 180.589), EPA assessed dietary exposures from boscalid in food as follows:

i. *Acute exposure.* There are no toxic effects attributable to a single (acute) exposure to boscalid; therefore an acute reference dose was not established for boscalid and an acute dietary exposure assessment is not needed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) Continuing Survey of Food Intake by Individuals (CSFII) 1994–1996 and 1998. As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues. The Agency did not use anticipated residue estimates or percent crop treated (PCT) information.

iii. *Cancer.* For the reasons described in Unit III.A, the Agency concluded that a quantitative risk and exposure assessment for cancer (either linear low-dose extrapolation or margin of exposure calculation) was not appropriate.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring 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 environmental fate characteristics of boscalid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the maximum estimated surface and ground drinking water concentrations (EDWCs) of boscalid for chronic exposures are 29.6 parts per billion (PPB) for surface water and 0.63 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The chronic dietary risk assessment used the surface water concentration value of 29.6 ppb to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control,

indoor pest control, termiticides, and flea and tick control on pets).

Boscalid is registered for use on sites that would result in residential exposure. From boscalid, residential exposure is only possible on golf courses and at ''U-Pick'' farms and orchards. A non-occupational dermal post-application exposure/risk assessment for these exposures was conducted in the previous occupational and residential exposure assessment and is described in the final rule in the **Federal Register** of July 30, 2003 (68 FR 44640) (FRL–7319–6).

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 EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional (''10X'') 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* In the 2-generation reproduction study in rats, body weight effects were seen in the mid and high doses in the second generation male pups. However, the degree of concern is low for the quantitative evidence of susceptibility seen in this study, since the body weight effects were seen in only one sex and only after dosing for two generations. There is a clear NOAEL for the body weight effects seen in the rat 2-generation reproduction study and EPA is regulating based on a point of departure below where these effects are seen.

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

While qualitative sensitivity was seen in the rabbit developmental study, the fetal effects were seen only at the limit dose in the presence of maternal toxicity. Further, since EPA is regulating based on a point of departure which is an order of magnitude below where these effects are seen in the rabbit developmental study, EPA concludes that the qualitative sensitivity evidenced in the fetuses in the rabbit developmental study does not require retention of the 10X children's safety factor.

3. *Conclusion.* The FQPA safety factor has been reduced to 1X for boscalid for the following reasons. First, EPA has a complete toxicity database for boscalid. The toxicity studies for boscalid show it generally to have low mammalian toxicity. Further, while data involving the testing of young animals did show increased quantitative sensitivity in the young with regard to body weight effects and qualitative sensitivity in one developmental study, clear NOAELs were identified for all of these effects. Moreover, the body weight effects at the LOAELs in these studies were either transient or inconsistent and qualitative sensitivity occurred at the limit dose in the presence of maternal toxicity. EPA concludes that there are no residual uncertainties for pre-natal and/or post-natal toxicity. The NOAEL used for various risk assessments would address the body weight effects seen at higher doses in the developmental and reproductive studies. Finally, EPA has conservatively estimated human exposure to boscalid, relying on worst case exposures in food (assuming all registered crops contain residues at the tolerance level), and conservative models as well as pesticide-specific data in estimating exposure from residues in drinking water and from residential uses.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* There were no toxic effects attributable to a single exposure to boscalid, therefore, neither an acute reference dose (aRfD) nor aPAD were established and acute dietary risk assessment and acute aggregate risk assessment are not required for boscalid.

2. *Chronic risk.* The unrefined chronic dietary risk assessment for boscalid was made using tolerance level residues, default and empirical processing factors and 100% CT assumptions. Results of this analysis indicate that chronic risk from the dietary (food + drinking water) exposure from boscalid will not exceed EPA's level of concern for the general U.S. population, and all population subgroups. The chronic dietary risk estimate for the highest reported exposed population subgroup, children 1-2 years old, is 33% of the cPAD. Chronic residential exposure from residues of boscalid is not expected; therefore the aggregate chronic risk is equivalent to the chronic dietary risk described above.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus average exposure to food and water (considered to be a background exposure level).

Boscalid is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate average food and water exposures with short-term non-occupational exposures for boscalid. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs, which are below the Agency's level of

concern. MOEs for the U.S. population, and all subpopulations of concern exceed 1,000. The level of concern for this assessment is for MOEs below 100.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate term, non-occupational exposures are anticipated from the use of boscalid, an intermediate-term aggregate risk assessment is not required for boscalid.

5. *Aggregate cancer risk for U.S. population.* Given the data showing no more than weak evidence of carcinogenic effects for boscalid, EPA concludes that boscalid poses no greater than a negligible risk of cancer.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatographic with mass spectrometric detection) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no Codex Maximum Residue Limits (MRLs) for boscalid. Canada has established MRLs for boscalid, but not for the crops that are in this rule.

V. Conclusion

Therefore, this regulation establishes tolerances for residues of boscalid,3-pyridinecarboxamide, 2-chloro-*N*-(4'-chloro[1,1'-biphenyl]-2-yl), in or on caneberry subgroup 13A, and bushberry subgroup 13B, respectively at 6.0 and 13 ppm; cotton, undelinted seed at 1.0 ppm; cotton, gin byproducts at 55 ppm; avocado at 1.5 ppm; sapote, black at 1.5 ppm; canistel at 1.5 ppm; sapote, mamey at 1.5 ppm; mango at 1.5 ppm; papaya at 1.5 ppm; sapodilla at 1.5 ppm; star apple at 1.5 ppm; cucumber at 0.5 ppm; and vegetable, root, subgroup 1A, except sugar beet, garden beet, radish and turnip at 1.0 ppm. In addition, this regulation establishes a time-limited tolerance for residues of boscalid in or on endive, belgian at 16 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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) or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 18, 2008.

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 removing the entry for berry group 13, and alphabetically adding the following commodities to the table in paragraph (a)(1), and by revising paragraph (b) to read as follows:

§ 180.589 Boscalid; tolerance for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Avocado	1.5
Bushberry, subgroup 13B	13.0
Caneberry, subgroup13A	6.0
Canistel	1.5
* * * * *	
Cotton, gin byproducts	55.0
Cotton, undelinted seed	1.0
Cucumber	0.5
* * * * *	
Mango	1.5
* * * * *	
Papya	1.5
Sapodilla	1.5
Sapote, black	1.5
Sapote, mamey	1.5
Star Apple	1.5
* * * * *	
Vegetable, root, subgroup 1A, except sugarbeet, garden beet, radish, and turnip	1.0
* * * * *	

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for the residues of the fungicide boscalid, 2-chloro-N-(4'-chloro [1, 1'-biphenyl]-2-yl)-3-pyridinecarboxamide in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. This tolerance will expire and is revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Endive, Belgian	16	12/31/09
Tangerine	2.0	12/31/08

* * * * *

[FR Doc. E8–6264 Filed 3–27–08; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0092; FRL–8357–4]

S-Abscisic Acid, Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the biochemical pesticide *S*-Abscisic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2Z,4E)-dienoic Acid in or on grapes when applied or used as a plant regulator in accordance with the terms of Experimental Use Permit 73049-EUP-4. Valent Biosciences Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *S*-Abscisic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2Z,4E)-dienoic Acid. The temporary tolerance exemption expires on October 1, 2010.

DATES: This regulation is effective March 28, 2008. Objections and requests for hearings must be received on or before May 27, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0092. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Chris Pfeifer, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703-308-0031; e-mail address: *pfeifer.chris@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: