

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 FFDCFA, 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: January 25, 2006.

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 180.447 is amended by increasing the tolerance level for the following commodities in the tables in paragraphs (a)(2) and (a)(3) to read as follows:

§ 180.447 Imazethapyr; tolerances for residues.

- (a)(1) * * *
- (2) * * *

Commodity	Parts per million
* * *	* *
Rice, grain	0.3
Rice, straw	0.4

(3)* * *

Commodity	Parts per million
* * *	* *
Crayfish	0.15
* * *	* *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0145; FRL–7757–9]

Boscalid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro [1,1'-biphenyl]-2-yl) in or on banana (imported), celery, and spinach. In addition, existing tolerances are being increased on almond hulls. Finally, the existing lettuce exception listed for the indirect or inadvertent residues in vegetables, leafy, group 4, is being revised to include celery and spinach, as well as lettuce. BASF requested the tolerances on almonds and bananas, and Interregional Research Project #4 (IR-4) has proposed group tolerances on vegetable, leafy, except brassica, Group 4 (to include celery and spinach), 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 February 8, 2006. Objections and requests for hearings must be received on or before April 10, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-OPP-2005-0145. All documents in the docket are listed on the www.regulations.gov website. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at <http://www.regulations.gov/>. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., 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.

FOR FURTHER INFORMATION CONTACT: Tony Kish, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9443; e-mail address: kish.tony@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), 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 E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background and Statutory Findings

In the **Federal Register** of July 6, 2005 (70 FR 38911) (FRL-7721-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filings of pesticide petitions (PP 4F6875, 3E6791, 5E6933) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709 and IR-4. The petition requested that 180.589 be amended by establishing a tolerance for residues of the fungicide boscalid, 3-pyridinocarboxamide, 2-chloro-N-(4'-chloro(1,1'-biphenyl)-2-yl, in or on the raw agricultural commodity almond, hulls at 15 parts per millions (ppm) (PP 4F6875), vegetable, leafy, except brassica, Group 4 at 50 ppm (PP 3E6791), and banana at 0.5 ppm (PP 5E6933). That notice included a summary of the pesticide petition prepared by BASF, the registrant. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV below.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will

result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

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

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 on almond hulls at 17 ppm, banana (imported) at 0.20 ppm, celery at 45 ppm, and spinach at 60 ppm. IR-4 requested a 50 ppm group tolerance for vegetable, leafy, except brassica in Group 4. However, the requested Boscalid tolerance for this entire group is inappropriate because the proposed 50 ppm group tolerance is substantially higher than the existing 11 ppm tolerance for the representative lettuce member of this group. Therefore, based on the submitted data, separate tolerances are established for the celery and spinach members in this group. The existing lettuce exception listed in 40 CFR 180.589(d) for indirect or inadvertent residues in vegetables, leafy, group 4, is being revised to include celery, and spinach, as well as lettuce. This is because of the separate tolerances established herein for celery and spinach in 40 CFR 180.589(a). EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as

the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by boscalid as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found in the **Federal Register** of July 30, 2003 (68 FR 44640) (FRL-7319-6).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases.

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).

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.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies

for Boscalid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (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 assessment was based on tolerance-level residues (in some cases modified by DEEM (Version 7.81) default processing factors), and assumed 100% crop treated.

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

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for boscalid in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of boscalid.

The Agency used 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 screening concentration in ground water (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. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD.

Based on the FIRST and SCI-GROW models, the estimated environmental concentrations (EECs) of boscalid for acute exposures are estimated to be 87.53 parts per billion (ppb) for surface water and 0.63 ppb for ground water. The EECs for chronic exposures are estimated to be 25.77 ppb for surface water and 0.63 ppb for ground water.

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).

Residential exposure to boscalid is 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 (ORE) assessment and is described in the final rule dated July 30, 2003 (68 FR 44640).

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to boscalid and any other substances and boscalid does not appear to produce a

toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that boscalid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* A complete discussion of the prenatal/postnatal sensitivity study was recently discussed in the final rule dated July 30, 2003 (68 FR 44640). No new information has been received to change this information. The Agency concluded that there are no residual uncertainties for pre- and post-natal toxicity as the degree of concern is low for susceptibility, as evidenced by the data in the studies for the rodent and non-rodent prenatal developmental, reproduction and fertility effects, and the acute, subchronic and developmental neurotoxicity studies.

3. *Conclusion.* There is a complete toxicity data base for boscalid and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. There is no evidence of susceptibility

following *in utero* exposure to rats and there is low concern and no residual uncertainties in the developmental neurotoxicity study after establishing toxicity endpoints and traditional uncertainty factors for intraspecies variability and interspecies extrapolation of 100X 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

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

2. *Chronic risk.* The chronic dietary exposure analysis was based on tolerance-level residues (in some cases modified by DEEM (Version 7.81) default processing factors), and assumes 100% crop treated. Even with these highly conservative assumptions, the risk estimates are well below the Agency's LOC. The most highly exposed population subgroup from DEEM is children 1–2 years, which has an exposure estimate of 0.067 mg/kg/day, and utilizes 31% of the chronic population adjusted dose (Cpad).

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). In this case, the non-occupational uses to be aggregated with dietary exposure are the turf use on golf courses and u-pick farms. Post-application exposures from these uses is considered short-term, and applies to adults and youth. Therefore, a short-term aggregate risk assessment was conducted. As all endpoints are from the same study, exposures from different routes can be aggregated. The exposure to residues in drinking water were included in the dietary exposure analysis. As a result, the aggregate exposure is the sum of two exposure values: Dietary (food + water) and residential. The target maximum daily exposure to boscalid residues is 0.22 mg/kg/day. The sum of the food, water, and residential exposures is 0.021 mg/kg/day. As a result, the short-term aggregate risk of exposure to boscalid residues is below the Agency's LOC. The exposure estimate was calculated using the general U.S. population, but is considered to be representative of 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.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Because no intermediate term, non-occupational exposures are anticipated from the use of Boscalid, boscalid is not expected to pose an intermediate-term risk.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography, mass spectrometry and electron capture 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 International or Codex maximum residue levels (MRLs) for boscalid.

C. Response to Comments

One comment dated 7/9/05 was received from B. Sachau. Ms. Sachau's comments regarding general exposure to pesticides contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to Boscalid, including all anticipated dietary exposures and other exposures for which there is reliable information. This comment as well as her comments regarding animal testing have been responded to by the Agency on several occasions. For example, 70 FR 1349 (January 7, 2005)(FRL–7691–4); 69 FR 63083 (October 29, 2004)(FRL–7681–9).

V. Conclusion

Therefore, tolerances are established for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'

chloro[1,1'-biphenyl]-2-yl), in or on banana (imported) at 0.20 ppm, celery at 45 ppm and spinach at 60 ppm. The existing 3.0 ppm tolerance on almond hulls is being increased to 17 ppm.

IR-4 requested a 50 ppm group tolerance for vegetable, leafy, except brassica in Group 4. However, the requested Boscalid tolerance for this entire group is inappropriate because the proposed 50 ppm group tolerance is substantially higher than the existing 11 ppm tolerance for the representative lettuce member of this group. Therefore, based on the submitted data, separate tolerances are established for the celery and spinach members in this group.

The existing lettuce exception listed in 40 CFR 180.589(d) for indirect or inadvertent residues in vegetables, leafy, group 4, is being revised to include celery, and spinach, as well as lettuce. This is because of the separate tolerances established herein for celery and spinach in 40 CFR 180.589(a).

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 EPA-HQ-OPP-2005-0145 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before April 10, 2006.

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 issue(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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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 (202) 564-6255.

2. *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 **ADDRESSES**. Mail your copies, identified by docket ID number EPA-HQ-OPP-2005-0145, to: Public Information and Records Integrity Branch, Information Technology and Resources Management 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 **ADDRESSES**. 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 issue(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: January 30, 2006.

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 as follows:

- a. In the table to paragraph (a)(1) by revising the entry for “Almond, hulls” and alphabetically adding commodities.
- b. In the table to paragraph (d) by revising the entry “Vegetable, leafy, group 4, except lettuce”.

§ 180.589 Boscalid; tolerances for residues.

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

Commodity	Parts per million
Almond, hulls	17
* * *	* *
Banana, import ¹	0.20
* * *	* *
Celery	45
* * *	* *
Spinach	60
* * *	* *

¹ No US registration as of January 31, 2006.

- * * *
- (d) * * *

Commodity	Parts per million
* * *	* *
Vegetable, leafy, group 4, except lettuce, celery and spinach	1.0
* * *	* *

DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 4

RIN 1094-AA49

Implementation of the Equal Access to Justice Act in Agency Proceedings

AGENCY: Office of the Secretary, Interior.
ACTION: Final rule.

SUMMARY: The Office of Hearings and Appeals (OHA) is amending its regulations that implement the Equal Access to Justice Act to bring them up to date with amendments to the statute that have been enacted since 1983.

DATES: *Effective Date:* February 8, 2006.

FOR FURTHER INFORMATION CONTACT: Will A. Irwin, Administrative Judge, Interior Board of Land Appeals, U.S. Department of the Interior, 801 N. Quincy Street, Suite 300, Arlington, Virginia 22203, Phone 703-235-3750. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800-877-8339.

SUPPLEMENTARY INFORMATION:

I. Background

OHA published a proposed rule on October 5, 2005, to update its regulations that implement the Equal Access to Justice Act (EAJA), 5 U.S.C. 504 (2000), 70 FR 58167-58175 (October 5, 2005). Those regulations were first promulgated in 1983. 48 FR 17596 (April 25, 1983). A section-by-section analysis of the proposed regulations was provided. 70 FR 58168-58170 (October 5, 2005).

We received one comment on the proposed rule, from Hobbs, Straus, Dean & Walker, LLP, on behalf of client Indian tribes and organizations. It “applaud[ed]” the proposed changes and recommended that they be made applicable to cases pending before OHA on the date the regulations become effective. We accept this suggestion. Although we proposed to omit section 4.604 (“Applicability to Department of the Interior proceedings”) of the 1983 regulations because it is no longer needed, 70 FR 58169 (October 5, 2005), we did not intend that the 1983 regulations would apply to cases pending when the new regulations became effective. We have added paragraph (b) to section 4.601 of the regulations to make our intention explicit that, when the new regulations become effective, they will apply to any EAJA application pending then or filed subsequently.